

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

**IN RE: ETHICON, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY  
LITIGATION**

**THIS DOCUMENT RELATES TO  
WAVE 1 / TVT-R CASES**

**Master File No. 2:12-MD-02327**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**RULE 26 EXPERT REPORT OF JERRY G. BLAIVAS, M.D.**

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. My opinions are as follows:

**I. QUALIFICATIONS**

Dr. Blaivas is a board certified urologist in the state of New York. He attended Tufts College for his bachelor's degree in 1964 and Tufts University School of Medicine for his medical doctorate in 1968. He completed a urology residency in 1976 after completing a general surgery internship followed by a two year general surgery residency. He has been teaching medicine since 1976 at Tufts University School of Medicine, Columbia University, Cornell University and most recently, SUNY Downstate Medical School. Throughout his academic career, Dr. Blaivas remained a practicing surgeon in a number of hospitals in Massachusetts and New York, and is currently an attending surgeon at The New York Presbyterian Hospital and Lenox Hill Hospital.

Dr. Blaivas is one of the pioneers of sling surgery for women with sphincteric incontinence. He performed his first autologous rectus fascial sling operation in 1981 and shortly thereafter modified the technique by creating a fascial graft instead of a fascial flap which was the prevailing method at the time. The reason for this change is that the flap was tethered by its abdominal attachments such that it was very difficult to place the sling loosely enough to avoid causing urethral obstruction. Once that modification was adapted, it was much easier to place the sling without any tension at all and that principle became the guiding principle for the subsequent development of synthetic mesh slings. In 1998, Dr. Blaivas, in a peer review journal, proposed that rectus fascial sling be considered a suitable operation for all women with sphincteric incontinence. Prior to that time, it was considered to be indicated only in women with complicated problems who had failed prior incontinence operations.

In the 1980's, Dr. Blaivas became acquainted with severe complications that resulted from synthetic mesh slings composed of Marlex and Mersilene. He performed a number of surgeries to remove these slings because of severe, refractory complications including pain, infection, erosion and urinary fistula. So difficult and problematic were these complications that Dr. Blaivas traveled to Toronto and spent some time with Ted Morgan, MD – a gynecologist who performed the largest number of these operations in the peer review literature. Dr. Morgan was considered to be a highly qualified surgeon, but even in his hands devastating complications occurred and they often occurred years after the original surgery. In the hands of less skilled surgeons, the complication rate was much higher. Dr. Blaivas discussed the surgical technique of sling surgery and methods of treating complications in great detail with Dr. Morgan. He concluded that: 1) even in the hands of a master surgeon, devastating complications could occur with synthetic slings, but rarely if ever occurred with autologous fascial (graft) slings; 2) in the hands of inexperienced surgeons, the complication rate could be unacceptably high; 3) removal of the mesh was exceedingly difficult and fraught with its own complications; 4) once a complication occurred, the chances of a successful outcome are low; and 5) the mesh itself, because it is a foreign body, contributes significantly to the complication rate. Because of these known complications and the technical difficulties performing mesh surgery, the operation fell out of favor until synthetic slings were revived, reinvented and promoted by industry through pervasive advertising and inducements to physicians to perform such surgeries.

Dr. Blaivas himself was heavily “recruited” by manufacturers of synthetic slings to become a “key opinion leader” and promote sling surgery. He was thoroughly vetted by industry representatives and Peter Petros, MD, one of the pioneers of synthetic sling surgery, spent a week with him in New York at his office and in the operating room discussing and demonstrating the theory and surgical technique of synthetic sling surgery. It was during this period of time that Dr. Blaivas decided to perform some synthetic slings in highly selected patients because the procedure could be performed so quickly and with so small an incision. Once he became adept at the technique through simulated training, he realized that there really wasn't any need for the “sling kit” that was supplied by the manufacturer. Further, he thought that the technique of passing the trocars from the vagina upwards to the abdomen was a much more dangerous technique that could lead to adjacent organ injury. So, instead, he fashioned a strip of “Gynemesh” and used a Stamey needle to pass the trocars from the abdomen to the vagina. He further modified the technique to include dissection alongside the urethra into the retropubic space, nearly eliminating the possibility of injuring the bladder or urethra or adjacent organs with the trocars.

In essence, Dr. Blaivas was using exactly the same technique he used for rectus fascial slings (which was considered the gold standard for incontinence surgery) and simply replaced the rectus fascial graft with a synthetic graft. Dr. Blaivas considered that synthetic slings, using the technique described here, could actually improve sling surgery provided that the new meshes were improved to the point that they had an acceptable safety profile and, in fact, he opined that synthetic slings will become the standard once the bugs were worked out. But to date, that has not happened. Throughout this time (the last decade of the 20th and first decade of the 21st century), Dr. Blaivas became increasingly aware of devastating, life threatening, and life style altering complications of synthetic sling surgery and became a world renowned expert at treating those complications. He has personally operated on about 75 – 100 patients with severe synthetic mesh

complications, and taken care of hundreds more who either did not elect further surgery or who simply gave up and were seeking relief from pain management experts. He has also discussed these issues with his peers. It is that experience, supported by peer-reviewed scientific literature, which forms the basis of the following opinions.

In August, 2015, Dr. Blaivas published the review article, “Safety considerations for synthetic sling surgery” in Nature Reviews Urology. The Nature family of journals is regarded as one, if not *the* premier resource for scientific research in the world.<sup>1</sup> Publication in Nature Reviews Urology, requires that the article meet strict criteria.<sup>2</sup> In its final version, the article was a herculean project - naming nine authors, spanning 29 pages, and containing 397 references. The exhaustive research presented in this paper further supports the opinions.

All of these opinions are to a reasonable degree of medical certainty. He applied the same scientific rigor that he use in all aspects of his professional activities, including caring for patients, publishing, lecturing, consulting with other health care professionals, and serving as a litigation expert. The methodology he used in rendering my opinions is the same that he uses in his professional activities. His opinions have been consistent over time and do not differ just because they are provided for various purposes or audiences.

Dr. Blaivas’ Curriculum Vitae is attached hereto and by reference made a part hereof. Please see Exhibit “A” attached.

## II. DISCUSSION OF OPINIONS

1. The Gynecare TVT-R is a polypropylene mesh product made and marketed by Ethicon to allegedly treat stress urinary incontinence (“SUI”). The TVT-R was the first polypropylene midurethral sling made and marketed for treatment of SUI. Its product consists of:

- PROLENE® polypropylene mesh (either Mechanically Cut Mesh (“MCM”) or Laser Cut Mesh (“LCM”)) with a polyethylene sheath or covering and attached trocars / surgical devices
- A TVT introducer
- A TVT Rigid Catheter Guide
- Instructions for use (IFU)

2. From the time it was introduced to the market through January 2015, the IFU for the TVT-R did not change. In January 2015, Ethicon introduced a new IFU with some modifications, as discussed below.

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<sup>1</sup> “The Nature Reviews clinical journals commission leaders in the field to write clinical content of the highest quality, authority and accessibility. Content is subject to rigorous review by our in-house editors and/or peer-review, and counsel is provided by the Editors-in-Chief and an international Advisory Boards to ensure comprehensive coverage of topical issues.” Nature.com accessed 12/18/2015.

<sup>2</sup> The criteria for publication include: Timely, accurate and balanced; Important for practicing doctors, researchers and academics in the subspecialty; Interesting and accessible to practicing doctors, researchers and academics in wider specialties. Nature.com accessed 12/18/2015.

3. The Gynecare TVT should not have been designed for placement in a surgically contaminated field<sup>3</sup> without proper animal and clinical studies to document safety and without a clear warning about the possibility of short and long term complications.<sup>4</sup> Bacteria attaches to mesh during the insertion process and can cause both acute and chronic infections in women.<sup>5</sup> Infection, even subclinical, can result in chronic inflammation, scarring, pain, abscess, vaginal, bladder and urethral erosion and other complications.

4. The Gynecare TVT causes serious and life-style altering complications including but not limited to chronic pelvic pain syndromes, chronic dyspareunia and sexual impairment, nerve injuries, de novo urinary symptoms, infections, fistulas, urethral obstruction, urethral strictures, bladder stones, death, vaginal, urethral, and bladder erosions, pelvic organ dysfunction, pelvic anatomy distortion, and other complications. These complications often require reoperation and are sometimes permanent. Because of these complications, the risks of these devices outweigh the benefits. I also am aware of many complications including deaths, injury to the iliac artery and vein, bowel injury and ureteral injuries despite the fact that virtually none of these complications were reported in the peer review literature.<sup>6</sup> Many of these complications can occur many years or even decades after the original surgery.<sup>7</sup>

5. The management of many sling complications is fraught with complexity and results in a high rate of persistent symptoms.<sup>8</sup> This has been evident since the complications from the Mersilene, Marlex, Gore-Tex, and Protogen slings that were performed during the last three decades of the 20th century and more recently the Protegen and Mentor ObTape slings. Further Ethicon knew or should have known about the contemporaneous complications that were occurring with their devices and with the devices of their competitors. From a scientific and ethical perspective, Ethicon should have had a high index of suspicion relating to the product defects based on the previous experiences with other synthetic products. For retropubic synthetic slings,

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<sup>3</sup> E.g., Culligan P, Heit, M., Blackwell, L., Murphy, M., Graham, C. A., & Snyder, J. Bacterial colony counts during vaginal surgery. *Infectious Diseases in Obstetrics and Gynecology*. 2003;11(3):161-5.

<sup>4</sup> E.g., Vollebregt A, Troelstra, A., & van der Vaart, C. H. . Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? *International Urogynecology Journal and Pelvic Floor Dysfunction*. 2009; 20(11):1345-51; Choi JJ, Palaniappa, N. C., Dallas, K. B., Rudich, T. B., Colon, M. J., & Divino, C. M. Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases. *Annals of Surgery*. 2012;255(1):176-80.

<sup>5</sup> E.g., Vollebregt, 2009; Choi, 2012; Klinge U, Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. Shrinking of polypropylene mesh in vivo: an experimental study in dogs. *The European Journal of Surgery*. 1998;164(12):965-9.

<sup>6</sup> E.g., Petri, 2012; Rogo-Gupta, 2013; Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. *Obstetrics and gynecology*. 2009;114(6):1287-94; Chohan HJ, Hutchings TB, Rooney KE. Dyspareunia associated with paraurethral banding in the transobturator sling. *American journal of obstetrics and gynecology*.

<sup>7</sup> Boyles SH, Edwards R, Gregory W, Clark A. Complications associated with transobturator sling procedures. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007;18(1):19-22; Parnell BA, Johnson EA, Zolnoun DA. Genitofemoral and perineal neuralgia after transobturator midurethral sling. *Obstetrics and gynecology*. 2012;119(2 Pt 2):428-31.

<sup>8</sup> E.g., Deng DY, Rutman, M., Raz, S., & Rodriguez, L.V. Presentation and management of major complications of midurethral slings: Are complications underreported? *Neurourology and Urodynamics*. 2007;26(1):46-52.

the most devastating complications are those that are due to vascular and bowel injuries and a number of deaths have been reported from these.<sup>9</sup>

6. The two most debilitating and challenging complication to treat are chronic pain and urinary fistulas. This pain can be located in the abdomen, pelvis, vagina, buttocks, perineum, groin, thigh, or leg. It can be acute (occurring immediately after surgery) or chronic with an insidious onset. It is often refractory to traditional treatments. It can be related to erosion; scarring; mesh deformation; entrapment or compression of large nerves with classic or atypical nerve distribution; entrapment of smaller nerve branches with diffuse distribution; muscular inflammation, scarring, trauma, and hypertonicity; visceral pain syndromes; and other complications. It can be associated with other sensory changes such as numbness and tingling.

7. Chronic Mesh Pain Syndrome (CMPS) has been described in the medical literature. The syndrome is characterized by the transformation of vaginal pain into a multi-organ system process. The pain is considerably greater and lasts longer than routine post-operative pain and treatment is extremely challenging.<sup>10</sup> The pain may continue, or even worsen, after mesh excision or revision. Completely new treatment modalities for pelvic pain have been developed as a response to this pain management challenge, including trigger point injections, nerve blocks, Botox injection, pelvic floor physical therapy, treatment with medications for chronic, neuropathic pain, and referral to contract-based pain management programs. These were extremely rarely used in urology or gynecology until the appearance of mesh-related pain.<sup>11</sup>

8. These and other complications may occur even in experienced hands and when proper surgical technique is used. Ethicon's marketing materials suggest that these complications occur mostly because of faulty surgical technique performed by inexperienced or poorly trained surgeons, perhaps by "over-tensioning" or misplacement. However, I have firsthand knowledge that is not the case. For example, I operated on one woman who had urethral erosion of synthetic mesh three years after it was implanted by one of our former fellows, whose expertise I am 100% confident of. Further, because of an unrelated episode of hematuria two years after implantation, she underwent cystoscopy which showed no signs of mesh erosion, yet one year later she was found to have erosion that also caused a urethral stricture. In the course of my practice, I have seen mesh complications from many world renowned experts, including physicians that Ethicon has retained as experts in litigation, and, from discussions with my colleagues, I know of many others. In the majority of cases that I see in my practice and that are reported in the literature, the device was placed in accordance with the manufacturers recommendations for placement.

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<sup>9</sup> E.g., ETH.MESH.00660488.

<sup>10</sup> E.g., Rogo-Gupta, 2013.

<sup>11</sup> E.g., Petri, 2012; Rogo-Gupta, 2013; Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, et al.

Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. *Obstetrics and gynecology*. 2009;114(6):1287-94; Cholhan HJ, Hutchings TB, Rooney KE. Dyspareunia associated with paraurethral banding in the transobturator sling. *American journal of obstetrics and gynecology*;202(5):481 e1-5; Boyles SH, Edwards R, Gregory W, Clark A. Complications associated with transobturator sling procedures. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007;18(1):19-22; Parnell BA, Johnson EA, Zolnoun DA. Genitofemoral and perineal neuralgia after transobturator midurethral sling. *Obstetrics and gynecology*. 2012;119(2 Pt 2):428-31

9. Even the simplest complications are often more complicated than they appear. It is commonly stated that when there is extrusion of the mesh through the vaginal wall, it is quite a simple thing to just trim the edges of the exposed sling and either create small vaginal wall flaps to cover the defect or simply leave the wound open and apply estrogen. However, the studies that report successful outcomes generally have a short follow-up and the outcomes may be much worse than they appear.<sup>12</sup> In my own personal experience, I have seen many patients who were treated this way who came back months, years, and even decades later with more extrusions and granulomas that proved almost impossible to “cure.”<sup>13</sup> These persistent and recurrent erosions are also reported in the medical literature and in Ethicon’s own documents.<sup>14</sup>

10. Given the increasing number of mesh sling operations performed and the complexity of surgery to repair the complications, there are an increasing number of patients who have failed initial treatments and an increasing number of “mesh cripples”. As more slings implantations are being performed and the longevity expectations of patients are increasing, it has become apparent that unanticipated, serious, and sometimes lifestyle- altering complications can occur that are not only unique to patients with slings but are also often refractory to treatment.<sup>15</sup> Other authors of recent peer-reviewed articles agree. Lee states that the use of synthetic material has generated novel complications, including mesh extrusion, pelvic and vaginal pain and mesh contraction, requiring a new classification system for complications relating to prosthesis insertion. He coined the term “Meshology” – an evolving field of sub-specialization dedicated to a growing population of affected women with complications from synthetic materials.<sup>16</sup> Barski also described mesh-related complications as “a current emerging problem, which confronts all urologists and gynecologists in their daily practice.”<sup>17</sup>

11. Ethicon knew or should have known about these serious, potentially life-threatening complications and specifically designed another sling (TVT-O) to attempt to avoid them as well as compete in the marketplace.<sup>18</sup>

12. The retropubic approach, such as that described in the Gynecare TVT IFU and taught by Ethicon, increases the risk and incidence of bladder perforations, bowel perforations, and other disastrous intraoperative events.<sup>19</sup>

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<sup>12</sup> E.g., Blaivas, 2015

<sup>13</sup> E.g., Reynolds WS, Kit, L., Kaufman, M.R., Karram, M., Bales, G.T., and Dmochowski, R. Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh. *The Journal of Urology*. 2012;187(5):1680-4.; Blaivas, 2013

<sup>14</sup> E.g., Petri, 2012; Abbott, 2014; Hansen, 2014; Unger, 2014; Rogo-Gupta, 2013; Shah, 2013; Dunn, 2014; Hammett, 2014; ETH.MESH.01706065 at 3.

<sup>15</sup> Blaivas 2015, 481.

<sup>16</sup> Lee 2015, 202.

<sup>17</sup> Barski and Deng 2015, p6.

<sup>18</sup> E.g., ETH.MESH.03932909.

<sup>19</sup> E.g., Brubaker, L., et al. (2011). "Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study." *Am J Obstet Gynecol* 205(5): 498 e491-496; Deng, 2007; Olagundoye, V. O., et al. (2007). "Delayed presentation of small bowel trauma during insertion of tension free vaginal tape (TVT) sling." *J Obstet Gynaecol* 27(1): 92-93.

13. Claims that make the procedure sound as if it is safer and easier to perform than it actually is are misleading. See above. Ethicon's initial concept for this product was sound – a simple, safe, efficacious, outpatient procedure that required minimal surgical skills and could be mastered by surgeons with little training. But the reality of the Gynecare TVT is very different from this concept. It is not easy to learn these techniques and the ergonomics of the trocars is such that, even for the most skilled surgeon, it is easy to misguide them and end up in the wrong anatomical location. There is ample evidence in the literature that it is very common for the trocars to inadvertently puncture the bladder or urethra during trocar passage.<sup>20</sup>

14. There is little margin of error when placing a retropubic sling, such as the Gynecare TVT. The procedure involves the blind passage of trocars through the vagina and passing through or in close proximity to the following structures: bladder, bowels, anterior vaginal wall, arcus tendineus fascia pelvis, urethra, the obturator neurovascular bundle, and venous plexus of Santorini and then out two small incisions above the pubic bone. If it is located too superficially (i.e., between the vaginal epithelium and the pubocervical fascia), vaginal extrusion might occur. Conversely, a Gynecare TVT that is too deep (i.e., to the pubocervical fascia) can cause urethral or bladder erosion. In my experience training fellows and residents, I was struck by what a difficult time they had finding the correct plane, how much bleeding they got into during the dissection and how often they injured or almost injured the bladder or urethra during the dissection and/or passing the trocar. In fact, the bladder or urethra perforation occurred at a mean incidence of about 3% (range 0-16%).<sup>21</sup> Perforation of the bladder, bowel, urethra, or vagina during the original implantation surgery dramatically increases the risk of subsequent sling erosion 26 fold.<sup>22</sup>

15. Furthermore, the location of anatomical structures varies from individual to individual and even in the same individual, making accurate placement unpredictable. For example, positioning of the patient in various degrees of dorsal lithotomy position can impact the locations of nerves and blood vessels relative to surface landmarks. Further, the size of the obturator foramen and the bony pelvis can vary.<sup>23</sup> Since the Gynecare TVT normally passes dangerously close to vital structures, the anatomic and positional variations render trocar passage more hazardous than theoretic considerations would suggest.<sup>24</sup> Further, although bleeding can usually be controlled or is self-limited, nerve injuries can have disastrous long term consequences.

16. Removal of the Gynecare TVT-R is technically difficult and requires considerable surgical expertise that many implanting surgeons do not possess. Due to tissue ingrowth, it is very difficult

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<sup>20</sup> E.g., Bhoyrul S, Vierra MA, Nezhat CR, Krummel TM, Way LW. Trocar injuries in laparoscopic surgery. *Journal of the American College of Surgeons*. 2001;192(6):677-83; Shindel AW, Klutke CG. Urethral slings placed by the transobturator approach: evolution in the technique and review of the literature. *Curr Urol Rep*. 2005;6(5):385-92.

<sup>21</sup> E.g., Blaivas, 2015.

<sup>22</sup> E.g., *Id.*, Osborn, D. J. et al. Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation. *Int. J. Urol*. 11, 1167–1170 (2014).

<sup>23</sup> E.g., Whiteside JL, Walters MD. Anatomy of the obturator region: relations to a trans-obturator sling. *Int Urogynecol J Pelvic Floor Dysfunct*. 2004;15(4):223-6; Litwiller JP, Wells RE, Jr., Halliwill JR, Carmichael SW, Warner MA. Effect of lithotomy positions on strain of the obturator and lateral femoral cutaneous nerves. *Clinical anatomy*. 2004;17(1):45-9.

<sup>24</sup> E.g., Bhoyrul, 2001; Shindel, 2005.

and sometimes impossible to remove the entire mesh and, in most instances, there are remnants of mesh that remain. This is well documented in the medical and scientific literature.<sup>25</sup> Further, there is a high likelihood of injuring adjacent structures and failing to alleviate symptoms, especially those related to pain, during removal surgery. There is a high incidence of recurrent sphincteric incontinence, requiring yet another procedure to repair it – ideally an autologous sling. Remnants of the partially removed Gynecare TVT-R can also migrate.<sup>26</sup> All of these procedures create more scar tissue in the pelvis, which further compromises the functionality of the pelvic anatomy and causes additional complications for women.

17. When the sling has been incorporated into the wall of the urethra or bladder, it is necessary to excise a portion of those structures in order to completely remove the mesh and, in so doing, there is a high likelihood of causing an urethrovaginal or vesicovaginal fistula. I have seen a number of such complications.<sup>27</sup> In order to prevent these fistulas, it is necessary to reconstruct the lower urinary tract and this usually requires considerable surgical expertise and experience utilizing plastic surgery techniques.<sup>28</sup>

18. When fistulas complicate mesh sling surgery, the outlook is grave. Although the reported incidence of mesh related fistulas is low (less than 1%), the success rate of surgical repair is low, 40% in our published experience. I have personally repaired approximately 200 vesicovaginal fistulas and approximately 150 urethrovaginal fistulas. With respect to fistula repair, I am only aware of seven failures in my series, four of whom were associated with mesh slings.<sup>29</sup>

19. The Gynecare TVT is not safer or less invasive overall than the alternative procedures. Furthermore, I have seen no evidence that Ethicon studied or evaluated the safety and efficacy of the insertion technique it developed and sold as part of the Gynecare TVT device or researched potential alternatives to minimize complications. Even though the IFU says the procedure can be done under local anesthesia it also says it can be done using regional or general anesthesia. Ethicon knew that surgeons generally were more comfortable using general anesthesia and did not inform them that Ulmsten, the inventor of the device, had performed the procedure using local anesthesia and that using general anesthesia increased the risk of urinary retention and erosion and decreased the chance of successful outcomes for patients.<sup>30</sup>

20. Pubovaginal slings using autologous fascia are as effective as the Gynecare TVT. In my own personal series and according to several peer review meta-analyses and the AUA guideline panel the success rate for autologous slings is comparable to synthetic mesh slings.<sup>31</sup>

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<sup>25</sup> E.g., Blaivas, 2015; Blaivas, 2013; Shah, 2013.

<sup>26</sup> E.g., Blaivas, 2015

<sup>27</sup> E.g., Blaivas, 2014.

<sup>28</sup> E.g., Blaivas, 2008.

<sup>29</sup> E.g., Blaivas, 2014.

<sup>30</sup> E.g., ETH.MESH.04048515; ETH.MESH.00130934; ETH.MESH.00400955; Isenberg Dep., 11/6/13, 461:16-530:13; 553:15-554:21; 566:9-15.

<sup>31</sup> E.g., Ogah, J., Cody, D. J., & Rogerson, L. (2011). Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn*, 30(3), 284-291. doi: .1002/nau.20980; Wadie, B. S., Edwan, A., & Nabeeh, A. M. (2005). Autologous fascial sling polypropylene tape at

21. Pubovaginal slings using autologous fascia are safer than synthetic slings with respect to serious complications such as lifestyle altering pain, dyspareunia, vascular, erosion, bowel and lower urinary tract injury, and other complications. Although the reported incidence of urinary retention is slightly higher, much of the data to support that comes from an era before the importance of a tension free repair was known. Using current technique, urinary retention is comparable amongst autologous and synthetic slings.<sup>32</sup>

22. These types of serious complications do not occur or occur very rarely in the alternative surgical treatments for stress urinary incontinence (such as autologous fascia pubovaginal slings or the Burch procedure). Furthermore, when complications occur with pubovaginal slings using autologous fascia, they are easier to treat and rarely if ever result in the permanent, lifestyle altering complications mentioned above. In addition, when mesh is not involved, it is almost always possible to obtain a satisfactory result treating the complication, unlike the Gynecare TVT-R.<sup>33</sup>

23. In my own experience, performing thousands of rectus fascial slings, I have never injured the bladder, urethra, ureter or any adjacent organs except for two minor urethral injuries in women who had undergone multiple prior incontinence surgeries nor have we reported any nor have we reported any injuries in our case series.<sup>34</sup> Further, as a surgeon “of last resort” I have had the opportunity to care for at least a thousand women with complications of biologic slings, retropubic suspensions and vaginal repairs of incontinence and almost never have I seen complications of the magnitude of synthetic mesh sling complications that have become routine in my practice.

24. As a practicing surgeon, educator, academician, and editor/reviewer of scientific journals, I became aware of serious complications associated with synthetic mesh earlier than physicians in community practice. I first became aware of a death from a TVT sling approximately in 2000, but I already was including this fact in postgraduate lectures by 2002. The source of the information was first hand from the surgeon who performed the TVT. Industry (including Ethicon) representatives were present at meetings in which these complications were discussed by me and my colleagues. In addition, case reports appeared in the literature relatively soon after introduction of these devices and before clinical trials were completed. Further, complications appeared in the MAUDE database. As evidenced by Ethicon’s written materials, Ethicon downplayed these complications.

25. There is almost always a time lag between what is known by Industry and physicians such as myself and community physicians. This is due to the time it takes for the dissemination of information and the withholding of information by Ethicon. Community doctors are often unable to keep up with the vast amount of and rapid changes in the scientific literature. They generally rely on manufacturers, through their sales and other representatives, to provide complete and

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short-term followup: a prospective randomized study. *J Urol*, 174(3), 990-993. doi: .1097/01.ju.0000169492.96167.fe; Garcia-Urena, 2007

<sup>32</sup> E.g., Blaivas, J. G., & Chaikin, D. C. (2011). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and longterm outcome. *Urol Clin North Am*, 38(1), 7-15, v. doi: .1016/j.ucl.2010.12.002; Garcia-Urena, 2007.

<sup>33</sup> E.g., Blaivas, 2011; Blandon, R., Gebhart, J., Trabuco, E., & Klingele, C. (2009). Complications from vaginally placed mesh in pelvic reconstructive surgery. *Int Urogynecol J* 20, 523-531. doi: 10.1007/s00192-009-0818-9.

<sup>34</sup> E.g., Blaivas, 2011.

accurate information to them. Based on my interactions with company representatives (including Ethicon), and company (including Ethicon) promotional materials, synthetic slings were invariably described as effective, quick, having few complications, and easy to learn and perform.

26. Mesh complications are significantly under-reported.<sup>35</sup> Additionally many, if not most, patients who experience complications do not return to their original implanting surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are.

27. The overall risk of a negative outcome after SMUS implantation surgery is  $\geq 15\%$ .<sup>36</sup> We calculated these minimum risks: revision surgery for erosion and obstruction alone, 4.1%; chronic pain, 4.1%; recurrent or persistent SUI, 5.3%; and *de novo* refractory OAB 3.9%. Of note, in patients requiring mesh removal, recurrence of SUI has been reported in 10–60% of individuals. Transobturator sling complications differed from retropubic sling complications in type and severity.

28. Despite the limitations in determining the exact rate of MSUS complications, other researchers have come up with similar rates in recent literature. Barski and Deng reported that “the rate of mesh-related complications is about 15–25% and mesh erosion is up to 10% for POP and SUI repair. Mesh explantation is necessary in about 1-2% of patients due to complications.”<sup>37</sup> Lee reported the incidence of chronic/persistent pain following MUS placement varies from 0 to 30%. The authors cited that Petri and Ashok reported on the management of 280 cases of late sling complications (RP 210 and TO 70). Compared with the retropubic MUS group, the TOT group had greater number of complications related to persistent pain (10% TVTs vs 32% TOT tapes), dyspareunia (3 vs 18%) and tape-related infections (4 vs 18%).<sup>38</sup> These rates are in keeping with those reported in Nature.

29. Ethicon did not adequately warn doctors and patients about the possibility of serious, chronic and lifestyle altering nature of the complications associated with its products, such as the Gynecare TVT, which included chronic and debilitating pain, chronic dyspareunia and sexual dysfunction, nerve injuries/entrapment, groin and leg pain, vaginal scarring, bladder dysfunction, bladder stones, recurrent urinary or bladder infections, recurrence, refractory overactive bladder and refractory sphincteric incontinence, the need for multiple corrective surgeries that may not resolve the symptoms, the marked difficulty removing the mesh sling and that even worse complications may ensue from mesh removal, the difficulties that occurred in treating the

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<sup>35</sup> E.g., Deng, 2007; Anger JT, Litwin, M. S., Wang, Q., Pashos, C. L., & Rodriguez, L. V. . Complications of sling surgery among female Medicare beneficiaries. *Obstetrics & Gynecology*. 2007;109(3):707-14; Blaivas, 2015; Dunn, 2014

<sup>36</sup> Evaluating the incidence, severity and consequences of the various RP and/or TOT sling complications is a daunting task. The reasons are varied include factors such as the failure of most of the thousands of articles regarding SMUS to track complications in any meaningful way; short-term follow-up and patients lost to follow-up; new, previously unrecognized complications such as banding as a cause of dyspareunia; absence of severity descriptions of pain; different complication profiles with different slings; and failure to address outcomes (including recurrent SUI) following corrective surgeries.

<sup>37</sup> Barski and Deng 2015, 2.

<sup>38</sup> Lee 2015, 205.

worsening of SUI following sling removal, and others.<sup>39</sup> Ethicon did not adequately warn physicians about the possibility that the complications above, including erosion, could occur months or years after placement of a synthetic sling, such as the Gynecare TVT.<sup>40</sup>

30. Ethicon did not adequately warn doctors and patients about the difficulty removing their products, such as the Gynecare TVT, nor did it warn them about the suboptimal and unpredictable results when mesh excision or revision becomes warranted due to complications. Very significantly, Ethicon did not attempt to train or educate doctors on how to best treat complications when they occur.<sup>41</sup>

31. The design of the Gynecare TVT is flawed because the product IFU does not accurately represent the nature of the inflammatory response and resulting scar tissue. Instead, the pre-2015 TVT IFUs state that "animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin layer of tissue, which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." Although Ethicon changed this language in January 2015 to remove the term "transient", it did not alert physicians that: (1) the mesh creates dense scar tissue not a "thin layer of tissue;" or (2) that the mesh is subject to degradation and weakening upon implantation.<sup>42</sup>

32. The design of the TVT-R is also flawed because the product's IFU does not accurately and completely represent the nature of the potential complications that women can suffer. It simply lists an almost encyclopedic number of adverse events with a kind of equanimity that minimizes the impact on patients and conveys to the doctor the impression that although these things might occur, they are very rare. For example, it states that one or more revision surgeries may be necessary but does not mention the well-known fact that these operations can be very difficult to do, requires great expertise and the results are often sub optimal. Further, the IFU does not even mention the severity and life style altering nature of some of these complications.

33. In addition, the IFU incorrectly states that the TVT-R is "tension-free." In reality, it is extremely difficult to correctly "tension" the sling. If placed even slightly too snugly, the tape may cause temporary or permanent lower urinary tract obstruction. This is compounded and the problems increase over time as the TVT-R shrinks in a woman's body. On the other hand, if the sling is applied too loosely, incontinence will persist.

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<sup>39</sup> E.g., ETH.MESH.03427878; ETH.MESH.02340504; ETH.MESH.05222673; ETH.MESH.02340471; ETH.MESH.02340306; ETH.MESH.05225354.

<sup>40</sup> E.g., *Id.*

<sup>41</sup> Blaivas, 2013; Unger, C., Abbot, S., Evans, J., Jallad, K., Mishra, K., Karram, M., Iglesia, C., Rardin, C., Barber, M. Outcomes following treatment for pelvic floor mesh complications. *Int Urogynecol J.* DOI 10.1007/s00192-013-2282-9.

<sup>42</sup> E.g., ETH.MESH.05588123; Barbolt Dep. 01/08/14, 409; 516-17; Hinoul Dep. 4/5/12 99:09-25; 4/6/12 518:14520:20; 6/26/13 175:1-176:17; 184:18-22; 328:10-24; Owens Dep. 9/12/2012 98:11-99:07; ETH.MESH.00870466; ETH.MESH.01218361; Holste Dep. 7/29/13 51:3-53:6; Vailhe Dep. 6/21/13 383:8-19; 1/2015 TVT IFU from Ethicon website.

34. The pre-2015 IFUs are also inadequate in that it represents complications as “transitory”:

Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.<sup>43</sup>

This language is not correct – the complications can be permanent, not transitory as Ethicon states. I agree with Ethicon’s Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., who stated “Pardon me again, from what I see each day, these patient experiences are not “transitory” at all.”<sup>44</sup> Although this language was deleted in January 2015 and replaced with language that reads “Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur,” this language was added too many years after Ethicon was aware of the chronic nature of the problems women can experience and still does not adequately warn physicians and patients about the complications associated with the TVT-R device.

35. Published reports on long-term outcomes of patients after mesh removal surgery are limited. Most authors of studies in this area commented on the technical difficulties encountered during mesh excision surgery and the fact that many (and in some series, most) patients require two or more surgeries; thus, even in the short term, outcomes are often suboptimal. Beyond the immediate intra-operative risks lays ahead the concern for secondary urinary incontinence and its management. At least one-third of patients undergoing sling excision surgery develop recurrent SUI. Treatment of persistent pain in patients with a SMUS is particularly challenging and has been entirely empirical and progressive in nature. Chronic disabling pain is one of the most common indications for mesh removal<sup>45</sup> Barski also described the difficulty treating pain caused by mesh slings with only 28% reporting a relief of symptoms postoperatively. Particularly difficult and traumatic for the pelvic floor were the excisions of transobturator tapes, according to the Barski review.<sup>46</sup> Lee also described pelvic pain and dyspareunia (up to 24% following MUS) as a “most distressing and potentially irreversible complication to treat.”<sup>47</sup> The etiology of chronic pain after MUS surgery is multifactorial. A complex interplay of factors can be causative, including synthetic material type, nerve and muscle injury, infection, contraction, erosion or extrusion.<sup>48</sup>

36. Ethicon would have known about these serious complications if proper clinical trials had been performed. Appropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT-R. Because of the known complications, many occurring years after the original surgery, well conducted, long term clinical trials (or a registry) would have demonstrated the extent and nature of these devastating complications.

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<sup>43</sup> ETH.MESH.03427878; ETH.MESH.02340504; ETH.MESH.05222673; ETH.MESH.02340471; ETH.MESH.02340306; ETH.MESH.05225354. *Also* Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7

<sup>44</sup> ETH.MESH.04093125.

<sup>45</sup> Blaivas 2015, 494.

<sup>46</sup> Barski and Deng 2015, p6.

<sup>47</sup> Lee 2015, 2

<sup>48</sup> Lee 2015, 205.

37. The medical literature surrounding the Gynecare TVT-R and other synthetic slings, is seriously flawed for reasons including, but not limited to, industry sponsorship, researcher bias, publication bias, industry manipulation of data, inappropriate choice of outcome variables, and lack of long-term follow-up.<sup>49</sup> In the Nature review, we noted the poor quality of many of the studies assessing risks of SMUS-associated complications. Deficiencies include the absence of sufficiently explicit outcome data due to the validation instruments used, the lack of long-term data, the loss of patients to follow-up, and the failure to distinguish between different products - to name a few. The poor quality of many of the studies on SMUS has been confirmed by other authors as well. Brubaker reported on missing data in two large SUI trials, TOMUS and SISTER.<sup>50</sup> Barski, in performing the meta-analysis on mesh complications, found no randomized trials on the surgical treatment of mesh complications and also decried the poor quality of the studies.<sup>51</sup>

38. Ethicon would have known about these serious complications if proper clinical trials had been performed. Appropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT. Because of the known complications, many occurring years after the original surgery, well conducted, longterm clinical trials (or a registry) would have demonstrated the extent and nature of these devastating complications.

39. The medical literature surrounding the Gynecare TVT and other synthetic slings, is seriously flawed for reasons including, but not limited to, industry sponsorship, researcher bias, publication bias, industry manipulation of data, inappropriate choice of outcome variables, and lack of long-term follow-up.<sup>52</sup> For example, internal Ethicon documents included a contract between Ethicon and Medscand Medical A.B. in which it was to receive payment contingent upon certain predetermined study outcomes. Payments to Medscand were conditioned upon the completion of studies by a predetermined date.<sup>53</sup> According to the agreement, Ethicon was the owner of any of work resulting from Ulmsten's studies.<sup>54</sup> The contract and payments were subject to Ulmsten's results regarding perioperative and postoperative complications, efficacy, and safety not varying "significantly" from Ulmsten's original publication (Int. Urogynecol J 1996-7:81-86).<sup>55</sup> The data used by Ulmsten and Nilsson in their initial and follow up publications was flawed and they failed to disclose the unexplained patient loss to follow up and an adverse event.<sup>56</sup> The 5-year follow up study also fails to report the patient loss to follow up or explain why only three of the original six centers were being included.<sup>57</sup> The 17-year follow up authored by Nilson also had a significant loss to follow up and only 51% of patients were evaluated in person.<sup>58</sup>

<sup>49</sup> E.g., Blaivas, 2015; ETH.MESH.00262089; ETH.MESH.00658508; ETH.MESH.03918253

<sup>50</sup> Brubaker L, et al. Missing data frequency and correlates in two randomized surgical trials for urinary incontinence in women. Int Urogynecol J. 2015; 26:1155-1159.

<sup>51</sup> Barski D and Deng DY. Management of mesh complications after SUI and POP repair: Review and analysis of the current literature. Biomed Res Int. 2015;2015:831285, p2. Doi: 10.1155/2015/831285. [Epub 2015 Apr 20].

<sup>52</sup> E.g., Blaivas, 2015; ETH.MESH.00262089; ETH.MESH.00658508; ETH.MESH.03918253.

<sup>53</sup> E.g., ETH.MESH.08696084.

<sup>54</sup> E.g., ETH.MESH.08696084 at 08696116.

<sup>55</sup> E.g., ETH.MESH.08696084 at 08696132.

<sup>56</sup> E.g., ETH.MESH.00371496 at 00371587; Ulmsten data; Nilsson Int Urogynecol J 2001.

<sup>57</sup> E.g., *Id.*

<sup>58</sup> E.g., Blaivas, 2015.

Furthermore, a randomized study involving the TVT reported significantly lower objective success rates than those reported by Ulmsten and Nilsson.<sup>5960</sup>

40. Many authors have signed contracts with mesh manufacturers and have acted as paid consultants for mesh manufacturers. These contracts often contain language that prevents company consultants from reporting or discussing device complications without written company approval. In some articles, these conflicts are not disclosed.<sup>61</sup>

41. Endorsement of these products by professional societies (e.g. the AUGS and SUFU Guidelines Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence) is biased because presents a one sided perspective. These paper cite the safety and efficacy of mesh slings, yet never even mentions the word complication. Further there is no conflict of interest statement or disclaimer despite the fact that several of the authors of the papers have financial interests with from mesh manufacturers.<sup>62</sup>

42. Underreporting of SMUS complications is also well-documented in the medical literature and discussed in the Nature article. Discrepancies exist between the SMUS complication rates reported by urologists from individual institutions, those reported in the literature, the (unreported) experience of tertiary care practices and those in the MAUDE (Manufacturer and User Facility Device Experience) database.<sup>63</sup> In our Nature review, we determined that approximately 88,000 removal surgeries should have been performed (based on published rates), and yet only a small fraction of such procedures are reported in the peer-reviewed literature.<sup>64</sup> Use of imperfect research methodologies, a lack of long-term follow up and reporting bias have been suggested as causes of these differences.<sup>65</sup>

43. Some authors and key opinion leaders have signed contracts with mesh manufacturers and have acted as paid consultants for mesh manufacturers. These contracts often contain language that prevents company consultants from reporting or discussing device complications without written company approval. In some articles, these conflicts are not disclosed.<sup>66</sup>

44. The Prolene mesh in the TVT-R can be either Mechanically Cut (MCM) or Laser Cut (LCM) in the manufacturing process.<sup>67</sup> Each carries its own unique problems for women.

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<sup>59</sup> E.g., Albo, M. et al. Treatment success of retropubic and transobturator mid urethral slings at 24 months. J. Urol. , 2281–2287 (2012).

<sup>60</sup> E.g., ETH.MESH.00262089; ETH.MESH.08692936; ETH.MESH.02123291; ETH.MESH. 8696084.

<sup>61</sup> E.g., ETH.MESH.04982735; ETH.MESH.05125268; ETH.MESH.05342590; ETH.MESH.09143435; ETH.MESH.04982748; ETH.MESH.08073794; ETH.MESH.08073801; ETH.MESH.08307690; ETH.MESH.09293114.

<sup>62</sup> Blaivas 2015, 481-509, 484.

<sup>63</sup> Blaivas 2015, 481-509, 485.

<sup>64</sup> Blaivas 2015, 481-509, 485.

<sup>65</sup> E.g., ETH.MESH.00262089; ETH.MESH.08692936; ETH.MESH.02123291; ETH.MESH.08696084

<sup>66</sup> ETH.MESH.09951087; Deposition of Dan Smith, May 15, 2014, 48:11-17

45. MCM can cause problems of fraying and deformation. Numerous complaints of the Gynecare TVT fraying and deforming during the implantation were reported to Ethicon.<sup>68</sup> Between launching the Gynecare TVT and November of 2003, Ethicon received 58 such complaints. According to these complaints, the fraying became more apparent when the color of the Gynecare TVT was changed from clear to blue.<sup>69</sup> Physicians also reported to Ethicon that the “crumbling” of the Gynecare TVT was worsened when the product was stretched or when the protective sheaths were removed during surgery.<sup>70</sup> An Ethicon engineer stated the “root cause” of the particle loss was the mechanical cutting of the polypropylene mesh and that changing the method of cutting could significantly limit the fraying of the mesh.<sup>71</sup> Ethicon documents confirm that the particle loss for the mechanical cut Gynecare TVT-R rates higher than the synthetic slings of other manufacturers.<sup>72</sup>

46. The polypropylene mesh used in the Gynecare TVT deforms *in vivo*. The deformation includes curling, cording, roping, rolling, deformation, loss of pore size with tension, and fraying. This deformation leads to pain and contracture and other complications.<sup>73</sup> Ethicon documents clearly illustrate the Gynecare TVT roping, curling and deforming when subjected to tension or elongation.<sup>74</sup> The roping, curling, deformation, particle loss and degradation was greater with the mechanically cut mesh than with the laser cut mesh.<sup>75</sup>

47. The mechanically cut Gynecare TVT also has “sharp edges”, which can cause adverse clinical complications in women such as erosion and abrasions and others.<sup>76</sup> Ethicon also received concerns from physicians that these sharp edges were causing complications in patients, including increased erosions.<sup>77</sup>

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<sup>68</sup> E.g., ETH.MESH.03905472; ETH.MESH.02621559; ETH.MESH.01813975; ETH.MESH.05644163; ETH.MESH.01809082.

<sup>69</sup> E.g., ETH.MESH.00541379; ETH.MESH.00863391; ETH.MESH.02180833; ETH.MESH.02180828.

<sup>70</sup> ETH.MESH.00858252

<sup>71</sup> E.g., ETH.MESH.01813975.

<sup>72</sup> ETH.MESH.01221055; ETH.MESH.00585842; ETH.MESH.01219629; ETH.MESH.01221024; ETH.MESH.00585823

<sup>73</sup> E.g., Klinge, 1998 (Shrinking); Feiner, 2010; Ostergard DR. Lessons from the past: directions for the future. Do new marketed surgical procedures and grafts produce ethical, personal liability, and legal concerns for physicians? Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(6):591-8; Jacquetin, 2009; Tunn R, Picot A, Marschke J, Gauruder-Burmester A. Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound in obstetrics & gynecology: the official journal of the International Society of Ultrasound in Obstetrics and Gynecology. 2007;29(4):449-52.

<sup>74</sup> E.g., ETH.MESH.00294195 (Moalli, P. A., et al. (2008). "Tensile properties of five commonly used mid-urethral slings relative to the TVT." Int Urogynecol J Pelvic Floor Dysfunct 19(5): 655-663); ETH.MESH.00440005; ETH.MESH.00302390.

<sup>75</sup> E.g., ETH.MESH.08334245; ETH.MESH.00440005; ETH.MESH.00302390.

<sup>76</sup> E.g., ETH.MESH.09656790.

<sup>77</sup> E.g., ETH.MESH.06696589; ETH.MESH.00330760; ETH.MESH.03911107; ETH.MESH.02620354; ETH.MESH.02625055; ETH.MESH.02653814; ETH.MESH.02652985; ETH.MESH.03715978; ETH.MESH.02630134; ETH.MESH.02628698; ETH.MESH.02626378; ETH.MESH.02622954; ETH.MESH.02622456; ETH.MESH.18882038

48. LCM means that the plastic mesh is cut into strips using a laser instead a cutting blade.<sup>78</sup> The result is that the mesh itself is stiffer than mechanically cut mesh. In fact, an internal memo from Becky Leibowitz to Paul Parisi and Dan Smith in late 2004 found that when the laser cut mesh was stretched it became about three times stiffer than the machine-cut TVT mesh.<sup>79</sup> Just four years later, in meeting notes, it is noted that there is a consensus that laser cut mesh is more rigid and stiff and that no clinical study has been done regarding the differences between laser cut mesh and mechanical cut mesh. The notes further indicate potential benefits of using mechanical cut mesh over laser cut mesh noting a lower rate of erosions, tensioning would be more similar to current products, and the edges of mechanical cut mesh might allow for an easier insertion.<sup>80</sup>

49. Importantly, most surgeons using the TVT products did not know what type of mesh (LCM or MCM) they were using.<sup>81</sup> Thus, there is no way for doctors to adjust tensioning differently or be aware that the mesh is stiffer, or to warn patients of an increased risk of erosions. The difference in the stretch profile between mechanically cut and laser cut mesh also led Carl G. Nilsson and Christian Falconer, two of the inventors of the original TVT,<sup>82</sup> and Jean de Leval, the inventor of TVT-O, to refuse to use, and question the use, of laser cut mesh.<sup>83</sup>

50. Moreover, use of the laser cut mesh would make them unable to rely on the original studies and data they use to tout the safety and effectiveness of the original TVT.<sup>84</sup> This data is something Ethicon wanted to rely on for all TVT-R products.<sup>85</sup> Additionally, laser cut mesh was never assessed on its own in a clinical trial.<sup>86</sup> Finally, the rigidity of the laser cut mesh can cause a higher incidence of erosion and sexual dysfunction than mechanically cut mesh.<sup>87</sup>

51. It is well established in the medical and scientific literature that heavier weight, smaller pore sized mesh such as that used in the Gynecare TVT-R elicits a greater inflammatory and fibrotic reaction in women.<sup>88</sup>

52. Despite moving to a lighter weight, larger pore sized mesh for its hernia products in the late 1990's and for its pelvic organ prolapse products so as to minimize the body's inflammatory and foreign body reaction to the polypropylene devices, Ethicon continued to manufacture the Gynecare TVT-R from the heavier weight, smaller pore sized mesh, ignoring the increased risks to patient safety and product efficacy.<sup>89</sup>

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<sup>78</sup> Lamont Dep. (9/11/13) 12:13-13:14

<sup>79</sup> ETH.MESH.01809080

<sup>80</sup> ETH.MESH.03916716

<sup>81</sup> ETH.MESH.09911296; ETH.MESH.09951087

<sup>82</sup> ETH.MESH.16416002, ETH.MESH.04048515

<sup>83</sup> ETH.MESH.03916716

<sup>84</sup> ETH.MESH.06040171; ETH.MESH.01706065

<sup>85</sup> Trial Testimony of Katrin Elbert, *Perry v. Luu, et al.*, (2/11/15) 3328-30

<sup>86</sup> ETH.MESH.03941617

<sup>87</sup> ETH.MESH.00294195; ETH.MESH.03916716; ETH.MESH.01706065; ETH.MESH.03923121

<sup>88</sup> E.g., Klinge U, Junge K, Stumpf M, Ap AP, Klosterhalfen B. Functional and morphological evaluation of a lowweight, monofilament polypropylene mesh for hernia repair. *Journal of biomedical materials research*; 63(2):129-36; Klosterhalfen, 2005.

<sup>89</sup> E.g., ETH.MESH.07455220; ETH.MESH.09275875; ETH.MESH.02268619; ETH.MESH.02589032; ETH.MESH.01264260; Smith Dep. (2/3/2014) 723:9-724:6, 829:16-829:19; Burkley Dep. (5/22/13) 184:17-24

53. The Gynecare TVT-R should not have been designed for permanent implantation in the human body without proper animal and human studies because the polypropylene used therein can elicit a permanent and persistent inflammatory response<sup>90</sup> and can create dense scar tissue.<sup>91</sup> Ethicon internal documents confirm it was aware of problems contemporaneously.<sup>92</sup>

54. The polypropylene mesh used in the Gynecare TVT-R creates scar plate that can entrap nerves, smooth muscle, and striated muscle and causes other tissue abnormalities.<sup>93</sup> Pore size, density, weight and surface area are all factors involved in scar plate formation.<sup>94</sup> This increased scar plate formation has adverse clinical consequences in women, including distortion of the pelvic anatomy, chronic pain, dyspareunia and/or sexual impairment, bladder and/or bowel dysfunction and other complications. These forces can act on the entire structure of the Gynecare TVT-R.<sup>95</sup>

55. The polypropylene mesh used in the Gynecare TVT-R shrinks unpredictably and asymmetrically, influenced by individual response, bacterial contamination, anatomical location, and time.<sup>96</sup> Because of and the unpredictable amount of shrinkage, it is not possible for the surgeon to determine the proper amount of tension to apply and there is no procedure that is really reliably "tension-free". The consequences of mesh shrinkage are very significant, resulting in pain, dyspareunia, urinary symptoms, and other complications.

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<sup>90</sup> E.g., Klinge, 1998 (Shrinking):965-9; Clave, A., Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants, *I Urogynecol J*, 2010 21:261-270; Klinge U, Klosterhalfen B, Muller M, Schumpelick V, "Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias," *Eur J Surg*, 1998 (164:951-960); Klosterhalfen, B, Junge, K, Klinge, U, "The lightweight and large porous mesh concept for hernia repair," *Expert Rev. Med. Devices*, 2005 2(1); Binnebosel M, von Trotha K, Jansen P, Conze J, Neumann U, Junge K, "Biocompatibility of prosthetic meshes in abdominal surgery" *Semin Immunopathol*, 2011 (33:235-243).

<sup>91</sup> E.g., Heise, C. P., & Starling, J. R. (1998). Mesh inguinodynia: a new clinical syndrome after inguinal herniorrhaphy? *Journal Of The American College Of Surgeons*, 187(5), 514-518; Demirer, S., Kepenekci, I., Evirgen, O., Birsen, O., Tuzuner, A., Karahuseyinoglu, S., & Kuterdem, E. (2006). The effect of polypropylene mesh on ilioinguinal nerve in open mesh repair of groin hernia. *The Journal Of Surgical Research*, 131(2), 175-181; Klosterhalfen, 2005; Klinge, 1998 (Shrinking).

<sup>92</sup> E.g., Burkley Dep. (5/22/13) 184:17-24; ETH.MESH.05588123; Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17; 184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.

<sup>93</sup> E.g., Heise, 1998; Demirer, 2006; Klosterhalfen, 2005; Vervest, H., Bongers, M. & van der Wurff, A. Nerve injury: an exceptional cause of pain after TVT. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 6, 665-667 (2006); Iakovlev V., M. G., Blaivas J. (2014). "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]." *International Continence Society Meeting Annual Meeting*; ETH.MESH.01264260.

<sup>94</sup> E.g., Iakovlev, 2014; ETH.MESH.01264260

<sup>95</sup> E.g., Blaivas, J. G., et al. (2015). "Safety considerations for synthetic sling surgery." *Nat Rev Urol*

<sup>96</sup> E.g., Klinge, 1998 (Shrinking); Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstetrics and gynecology*. 2010;115(2 Pt 1):325-30; Mamy L, Letouzey V, Lavigne JP, Garric X, Gondry J, Mares P, et al. Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011;22(1):47-52; Letouzey V, Huberlant S, Lavigne J, Mares P, Garric X, De Tayrac R. Is polypropylene mesh coated with antibiotics is efficient to prevent mesh infection and contraction in an animal infectious model? [Abstract]. 37th Annual Meeting of the International Urogynecological Association. 2012:193; Jacquetin B, Cosson M. Complications of vaginal mesh: our experience. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009;20(8):893-6; Garcia-Urena MA, Vega Ruiz V, Godoy A, Baez Perea JM, Marin Gomez LM, Carnero Hernandez FM, et al. Differences in polypropylene shrinkage depending on mesh position in an experimental study. *Am J Surg*. 2007;193(4):538-42

56. In the Nature paper, we discussed the mechanisms for mesh-related complications. These include inflammatory reactions, fibrosis, deformation, nerve entrapment, degradation, shrinkage/contraction, migration, and stiffening. These material features of polypropylene mesh and their relationship to mesh complications are discussed in my expert report. Numerous recent peer-reviewed articles have confirmed the contribution of these properties into the mechanisms of mesh-related symptoms for patients.

57. Degradation was reported in papers by Iakovlev et. al and Imel et. al on the in vivo degradation of transvaginally implanted polypropylene products. Degradation progresses over time and results in clinically significant embrittlement, loss of flexibility mesh stiffening and deformation.<sup>97,98</sup> Bendavid reported on the mechanism of hernia mesh repair pain. This new clinical syndrome, characterized by slow onset, relentless progression, and uncompromising lack of response to treatment, was attributed to nerve entrapment incased in dense scar tissue. According to the author, the pores of mesh need to be viewed as “mini-compartments” of biological tissue where the vasculature, nerves and their receptors are exposed to potential mechanical and chemical factors: scarring, entrapment, compression, tugging, deformation, contraction, hypoxia/acidosis, inflammation and edema.<sup>99</sup> In another study by Bendavid et. al, a marked increase in nerve density trapped in scar was observed in patients who had mesh-related pain, regardless of the surgical technique or surgical location.<sup>100</sup> Testing by Lee also discussed the mechanisms of chronic pain after MUS surgery, describing a “complex interplay of factors [that] can be causative, including synthetic material type, nerve and muscle injury, infection, contraction, erosion or extrusion.”<sup>101</sup>

58. Questions have been raised in the peer-reviewed literature regarding the carcinogenic potential for transvaginally placed polypropylene mesh. We addressed this concern in our Nature review. These carcinogenic effects, leading to the development of sarcomas, have been studied in animal models. The basic research and clinical data suggest that implantation of polypropylene mesh might increase the risk of sarcoma. If a risk is present in humans, it is likely to be very low. Mutagenic effects, in general can take many years to accumulate and then a long period to cause a neoplasm. Detecting any oncogenic effects of SMUS implants would require a large cohort of patients with the same type of implant, and these patients would have to be followed up for a sufficiently long period of time, most likely at least 15 years.<sup>102</sup> However, a recent case of clear cell carcinoma associated with an eroded polypropylene sling was reported November, 2015 in the International Urogynecology Journal.<sup>103</sup> A second case of squamous cell carcinoma associated with a midurethral sling was reported at the same time. In an accompanying editorial in the same

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<sup>97</sup> Iakovlev VV, et al. Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. 2015:00B:000-000, p10.

<sup>98</sup> Imel A, et al. In vivo oxidative degradation of polypropylene pelvic mesh. Biomaterials. 2015 Dec;73:131-41, 132.

<sup>99</sup> Bendavid R, et al. Mesh-related SIN syndrome. A surreptitious irreversible neuralgia and its morphologic background in the etiology of post-herniorrhaphy pain. Int J Clin Med. 2014; 5:799-810, 799.

<sup>100</sup> Bendavid R, et al. A mechanism of mesh-related post-herniorrhaphy neuralgia. Hernia. 2015 Nov 23, p6. [Epub ahead of print].

<sup>101</sup> Lee 2015, 205.

<sup>102</sup> Blaivas 2015, 481-509, 500.

<sup>103</sup> Lin HZ, et al. A first reported case of clear cell carcinoma associated with delayed extrusion of midurethral tape. Int Urogynecol J. 2015 Nov 20. [Epub ahead of print].

journal issue, Goldman recognized that a cause-and-effect pattern could be concerning and recommended vigilance.<sup>104</sup> This is new information that supports my opinions that patients who receive mesh products should be monitored closely over a long-term period.

59. I have reviewed the Material Safety Data Sheet for the polypropylene used in the Gynecare TVT-R medical device and related documents. This document states in part, under INCOMPATIBILITY, that the following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid.<sup>105</sup> The Gynecare TVT-R should not have been designed using this polypropylene because many of these chemicals are routinely found in human tissue.

60. The polypropylene mesh used in the Gynecare TVT-R degrades *in vivo*.<sup>106</sup> Degradation has been reported to result in stiffening of the mesh and the presence of small molecular complexes and chemical products of degradation in surrounding tissues provides an additional stimulus for the chronic inflammatory response, which causes a continuous cycle of remodeling around the mesh filaments and extension of fibrosis.<sup>107</sup> *In vivo* it has been well documented that mesh also stiffens.<sup>108</sup> Dr. Iakovlev and I have recently published an abstract in a peer-review journal that describes mesh hardening, degradation, deformation, and nerve/muscle entrapment from a histological standpoint and how these findings relate to pain and other mesh complications.<sup>109</sup>

61. Ethicon's own internal document support my opinion that polypropylene mesh degrades in the body.<sup>110</sup>

All opinions are given to a reasonable degree of medical certainty. I reserve the right to amend or supplement this report if additional information becomes available. I also reserve the right to adopt all of my opinions in the other reports that I have submitted for the Wave 1 cases.

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<sup>104</sup> Goldman HB and Dwyer. Polypropylene mesh slings and cancer: An incidental finding or association? Int Urogynecol J. 2015 Nov 19, p2. [Epub ahead of print].

<sup>105</sup> ETH.MESH.02026591.

<sup>106</sup> E.g., Jongebloed WL, Worst JF. Degradation of polypropylene in the human eye: a SEM-study. Documenta ophthalmologica Advances in ophthalmology. 1986;64(1):143-52; Coda A, Bendavid R, Botto-Micca F, Bossotti M, Bona A. Structural alterations of prosthetic meshes in humans. Hernia : the journal of hernias and abdominal wall surgery. 2003;7(1):29-34; Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. Journal of biomedical materials research Part B, Applied biomaterials. 2007;83(1):44-9; Clave , 2010; Sternchuss G, Ostergard DR, Patel H. Post-Implantation Alterations of Polypropylene in the Human. J Urol. 2012;188(1):27-32

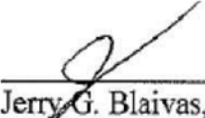
<sup>107</sup> E.g., Iakovlev, 2014; Junge, 2001; Blaivas, 2015.

<sup>108</sup> E.g., Costello, 2007 (Materials); Fayolle B, Audouin L, Verdu J. Oxidation induced embrittlement in polypropylene - a tensile testing study. Polymer Degradation and Stability. 2000;70(2000):333-40; Fayolle B, Audouin L, Verdu J. Initial steps and embrittlement in the thermal oxidation of stabilised polypropylene films. Polymer Degradation and Stability. 2002;75:123-9; Fayolle B, Audouin L, George GA, Verdu J. Macroscopic

<sup>109</sup> Blaivas, 2015

<sup>110</sup> ETH.MESH.07690752; DEPO.ETH.MESH.00004755; ETH.MESH.12831391; ETH.MESH.02589032; ETH.MESH.07192929; ETH.MESH.01264260; Burkley Dep., May 23, 2013 at 315:8-13.

This 1<sup>st</sup> day of February, 2016.

  
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Jerry G. Blaivas, MD

### **III. FACTS OR DATA CONSIDERED IN FORMING OPINIONS**

In addition to the references included herein, an Index is attached hereto and by reference made a part hereof. Please see **Exhibit “C”** attached.

### **IV. COMPENSATION**

Dr. Blaivas’ Fee Schedule is attached hereto and by reference made a part hereof. Please see **Exhibit “B”** attached.

### **V. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS**

Merjem Delija v. Neil Sayegh, etc.; index no. 14449/2003

Jose Cuevas v. the Mount Sinai medical Center; Index no. 0017209/2004

Randy Smith, et al. v. Andrew Chan, M.D., et al.; Index No. 024786/2009

Katelyn Vercher, et al. v. Chiari Institute, et al.; 2:09-cv-01751-AKT

Lisa Marie Fontes, et al. v. American Medical Systems, Inc.; 2:12-CV-02472

Debbie Jilovec, et al., v. American Medical Systems, Inc.; 2:12-CV-05561

Joann Serrano, v. American Medical Systems, Inc.; 2:12-CV-3719

Mary Weiler, et al. v. American Medical Systems, Inc.; 2:12-CV-05836

Carolyn F. Smothers v. Boston Scientific Corp.; 2:12-cv-08016

Katherine L. Hall v. Boston Scientific Corp.; 2:12-cv-08186

Julia Wilson v. Boston Scientific Corp.; 2012-02626

Ronda Orozco, et al., v. Boston Scientific Corp.; 2012-03068

Maria Cardenas v. Boston Scientific Corp.; 2012-02912

Diane Albright v. Boston Scientific Corp.; 2012-00909

Jo Huskey, et. al v. Ethicon, Inc.; 2:12-cv-05201

Tonya Edwards, et. al v. Ethicon, Inc.; 2:12-cv-09972

# Exhibit A

**Curriculum Vitae**

**Name:** Jerry G. Blaivas, MD

**Office Address:** 445 East 77th Street  
New York, NY 10075  
Tele: (212) 772 3900

**Citizenship:** United States of America

**Licensure:** New York #144945, January 1981

**Specialty  
Certification:** American Board of Urology, 1978

**Education:** Tufts University School of Medicine M.D., 1968  
Tufts College, B.A., 1964

**Post Graduate:**

Intern, General Surgery: Boston City Hospital  
Boston, MA  
1968 - 1969

Resident, General Surgery: Boston City Hospital  
Boston, MA  
1969 - 1971

Resident, Urology: Tufts-New England Medical Center  
Boston, MA  
1973 - 1976

**Military:** Major, United States Army Department of Orthopedics  
(Active Duty) Walson Army Hospital  
Fort Dix, NJ  
1971-1973

**Faculty  
Appointments:**

Adjunct Professor of Urology  
SUNY Downstate Medical School  
Brooklyn, NY  
2008 - present

Clinical Professor of Urology

Blaivas

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Weill Medical College of Cornell University  
New York, NY  
1993 - present

Professor of Clinical Urology  
College of Physicians & Surgeons  
Columbia University  
New York, NY  
1989 - 1993

Vice-Chairman, Department of Urology  
College of Physicians & Surgeons  
Columbia University  
New York, NY  
1987 - 1993

Director, Neurourology  
College of Physicians & Surgeons  
Columbia University  
New York, NY  
1981 - 1993

Associate Professor of Urology  
College of Physicians & Surgeons  
Columbia University  
New York, NY  
1981 - 1989

Associate Professor of Urology  
Tufts University School of Medicine  
Boston, MA.  
1979 - 1981

Assistant Professor of Urology  
Tufts University School of Medicine  
Boston, MA.  
1976 - 1979

Blaivas

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**Hospital and University**

**Administrative Appointments:**

Chief of Urogynecology  
Attending Surgeon (Urology)  
Lenox Hill Hospital  
New York, NY  
1999 - 2007

Attending Surgeon (Urology)  
The New York Presbyterian Hospital  
New York, NY  
1993 - present

Attending Urologist  
The Presbyterian Hospital  
New York, NY  
1992 - 1993

Director, Neurourology Laboratory  
The Presbyterian Hospital  
New York, NY  
1981 - 1993

Associate Attending Urologist  
The Presbyterian Hospital  
New York, NY  
1981 - 1992

Chief of Urology  
Helen Hayes Hospital  
West Havestraw, NY  
1987 - 1993

Assistant Surgeon  
New England Medical Center  
Boston, Massachusetts  
1976 - 1981

Director, Urodynamics Laboratory  
New England Medical Center

Blaivas

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Boston, MA  
1976 - 1981

Consultant in Urology  
Massachusetts Rehabilitation Hospital  
Boston, MA 1977 - 1981

Consultant in Urology  
Braintree Hospital  
Braintree, MA 1977 - 1981

Attending Physician, Surgical Service  
Boston Veterans Administration Medical Center  
Boston, MA  
1977 – 1981

**Professional  
Societies:**

American Association of Genitourinary Surgeons  
American Board of Urology  
American College of Surgeons  
American Urogynecologic Society  
American Urologic Society, New York Section  
American Urological Association  
Chilean Urologic Society, Honorary Member  
International Continence Society  
Massachusetts Medical Society (1973 - 1981)  
National Board of Medical Examiners  
New York Academy of Medicine  
Societe Internationale d'urologie  
Society for Urodynamics and Female Urology  
Society of Pelvic Surgeons  
Society of University Urologists

**Honors and  
Awards:**

Victor A. Politano Award, American Urological Association, 2009

Jerry G. Blaivas Honorary Lectureship, Society of Urodynamics and Female Urology,  
established 2007

Continence Care Champion, National Association For Continence, 2005

Blaivas

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Pfizer-American Urological Association Visiting Professor Award, 2004

The Best Clinical Study for the Year 2000.

Society for Urodynamics and Female Urology, 2000

Lifetime Achievement Award

Society for Urodynamics and Female Urology, 1999

Brantley Scott M.D. Award.

American Foundation for Urologic Disease, 1999.

J. Marion Sims Award

American Uro-Gynecologic Society, 1993

Best Doctors in America, 1992-present

Best Doctors in New York, 1992-present

Zimskind/Kendall Award

Urodynamic Society, 1985

First Prize for Research

Annual Meeting of the International

Continence Society, Leiden, 1982

Winner, Team Debate

Joint Meeting of the International

Continence Society and the Urodynamic

Society, Los Angeles, 1980

Commendations Medal

United States Army, 1973

Sword and Shield Honor Society

Tufts College, 1965

**Hospital and University**

**Committees:** Executive Committee  
Department of Urology  
College of Physicians & Surgeons  
Columbia University, 1981-1993

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Chairman, Quality Assurance Committee  
Department of Urology  
Columbia Presbyterian Medical Center  
1986 - 1991

Committee on Computer Development for Medical  
Applications, The Presbyterian Hospital  
1985 - 1993

Medical Evaluation Committee  
Columbia Presbyterian Medical Center  
1985 - 1987

Human Investigation Committee  
Department of Urology  
Columbia Presbyterian Medical Center  
1981 - 1993

Chairman, Patient Care Committee  
The Presbyterian Hospital  
1981 - 1986

Executive Committee  
Tufts University School of Medicine  
1978 - 1981

Doctor's Office Committee  
Columbia-Presbyterian Medical Center  
1988 - 1993

**Professional  
Committees:**

Executive Committee  
Society for Urodynamics and Female Urology  
1999-present

Chairman, Voiding Dysfunction Committee  
American Urological Association  
1996-2000

Advisory Board Member

Blaivas

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New York Menopause Center  
1996 - 2000

Bladder Health Council  
American Foundation for Urologic Diseases  
1996 - present

Guidelines Panel on Surgical Treatments for Female Urinary Incontinence American  
Urological Association  
1994 - Present

Executive Committee  
Urodynamics Society  
1993-1999

Chairman New Technology Council  
American Urological Association  
1993 - 1997

Guest Examiner  
American Board of Urology  
1992 - 1996

President  
Urodynamic Society  
1992 - 1993

Member, BPH Guidelines Panel  
Agency for Health Care & Policy Review  
1989 - 1996

Technical Advisor  
Incontinence Guideline Panel  
Agency for Health Care & Policy Review  
1989 - 1996

Practice Parameters & Guidelines Committee  
American Urological Association  
1991 - 1998

Member, Terminology Committee

Blaivas

8

American Urological Association  
1991 - 1993

Chairman, Biomedical Engineering Committee  
American Urological Association  
1990 - 1993

Vice-Chairman, New Technology Committee  
American Urological Association  
1990 - 1993

Vice President  
Urodynamic Society  
1989 - 1991

Examination Committee  
American Board of Urology  
American Urological Association  
1989 - 1993

Protocol Committee  
Measurement Committee  
AUA Cooperative BPH Study  
1989 - 1993

Member, ad hoc Committee on Female Urology  
American Urological Association  
1988 - 1993

Advisory Board, Continence Program for Women  
University of Virginia  
1988 - 1996

Program Committee, Annual Meeting of the  
American Urological Association  
1988 - 1995

Patient Management Technology Committee  
National Multiple Sclerosis Foundation  
1987 - 1991

Blaivas

9

Secretary, Urodynamic Society  
1986 - 1989

National Metric Council - Representative from the  
American Urological Association  
1986 - 1991

Chairman, Urology Sub-Committee  
American Society for Testing and Materials  
1986 - 1991

Co-Chairman, Annual Urodynamic Society Meeting  
1985

Program Committee, Combined Meeting of the  
International Continence Society and the  
Urodynamic Society  
1985

Vice-Chairman, Urology Sub-Committee  
American Society for Testing and Materials  
1985 - 1986

Program Committee, Annual Meeting of the  
American Urological Association  
1984 - 1986

Standardization Committee  
International Continence Society  
1983 - 1991

Medical Advisory Board, New York Chapter  
National Multiple Sclerosis Foundation  
1983 - 1991

Member-at-large  
Executive Committee, Urodynamic Society  
1982 - 1984

Program Chairman  
Annual Urodynamic Society Meeting, Boston

1981

Chairman, Nomenclature Committee  
Urodynamic Society  
1980 -1985

Education Committee  
National Multiple Sclerosis Foundation  
1980 - 1990

Neurophysiology Committee  
Urodynamic Society  
1980 - 1986

Program Committee, Combined Meeting of the  
International Continence Society and the  
Urodynamic Society  
1980

Biomedical Engineering Committee  
American Urological Association  
1980 - 1993

Chairman, Task force on Urodynamic Procedures  
Urodynamic Society  
1980 – 1984

**Editorial Positions:** Editor-in-Chief, Neurourology and Urodynamics  
1981 - 2007

Editorial Boards:    Neurourology & Urodynamics 1981 - present  
                              Contemporary Urology 1998 - 2007  
                              International Urogynecology Journal 2002 - present

Reviewer: British Journal of Urology  
International Urogynecology Journal  
Journal of Urology  
Urology  
Obstetrics & Gynecology  
The New England Journal of Medicine  
American Journal of Physiology

Blaivas

11

Brain  
Neurology

Consulting Committee: Urologia Integrada y de Investigacion

**Previous Grant Support:**

Smith Kline Beecham 1993 - 1995	Effects of once daily dosing with two dose levels of epristeride or placebo on the voiding detrusor pressure in patients with bladder outflow obstruction due to benign prostatic hyperplasia.
Eli Lilly 1993 - 1995	Duloxetine vs. placebo in patients with urinary incontinence - assessment of subjective & objective parameters. \$92,500
American Foundations Of Urologic Diseases Scholar Award (Faculty Sponsor) 1988 - 1990	Parameters of Detrusor Contractility \$50,000
National Multiple Sclerosis Society 1977 - 1978	The Diagnosis, Treatment and National History of Voiding Disturbances in Multiple Sclerosis Grant # RG1108-A-1 \$78,418
National Multiple Sclerosis Society 1978 - 1980	The diagnosis, treatment and national history of voiding disturbances in multiple sclerosis. Grant # RT1108-B-2 \$113,915
Merrell Research Center 1978	Effect of Oral Candicidin on on Benign Prostatic Hypertrophy, \$52,000
Smith, Klein & French 1982	Dose Range Study of Phenoxybenzamine in Benign

## Blaivas

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Prostatic Hypertrophy  
\$27,000

Eastern Paralyzed  
Veterans  
1983 - 1984  
Grant \$100,000

NeuroUrology Fellowship

Eastern Paralyzed  
Veterans  
1984 - 1985  
Training Grant \$17,000

Neurourology Nurse

Roerig  
Pharmaceuticals  
1984 - 1985

Geocillin in the Treatment of  
Recurrent Urinary Tract Infections  
Study # 83-R-003  
\$25,000

Roerig  
Pharmaceuticals  
1985-1986

Geocillin for the Treatment of  
Bacterial Prostatitis in Patients with Multiple  
Sclerosis or Spinal Cord Injuries with Associated  
Dysfunctional Urinary Bladders  
Study # 84-R-014  
\$18,000

American Federation  
For Aging (AFAR)  
1987 - 1988

Urodynamics of Aging  
AFAR CU50384501  
\$16,000

Embassy Arab  
Republic of Egypt  
Cultural and Educational  
Bureau Peace Fellowship  
Program

Bladder Outlet Obstruction  
PF # 2436 - \$17,000

Spinal Cord Research Parameters of Bladder  
Foundation  
1989 – 1990

Contractility in an In-vitro  
Rabbit Bladder Model, \$19,200

National Multiple  
1988 - 1991

Neurourodynamic Evaluation Sclerosis Foundation of Multiple Sclerosis  
Grant # RG1997-A-4

Blaivas

13

\$116,682

**PUBLICATIONS****Articles in Peer Review Journals:**

1. **Blaivas JG**, Pais, VM, Spellman, RM. Chemolysis of Residual Stone Fragments After Extensive Surgery for Staghorn Calculi. *Urology* 6:680-6, 1975.
2. **Blaivas JG**, Pais VM, Retik AB. Paraurethral Cysts in the Female Neonate. *Urology* 7:504-7, 1976.
3. **Blaivas JG**, Previte SR, Pais VM. Idiopathic Pelviureteric Varices. *Urology* 9:207-1, 1977.
4. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. A New Approach to Electromyography of the External Urethral Sphincter. *J Urol* 117:773-7, 1977.
5. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. Changing Concepts in the Urodynamic Evaluation of Children. *J Urol* 117:778-3, 1977.
6. **Blaivas JG**, Labib, KB. Urinary Retention in the Female: Complete Urodynamic Evaluation. *Urology* 10:383, 1977.
7. Rao CN, **Blaivas JG**. Primary Renal Artery Dissecting Aneurysms, A review. *J Urol* 118:716-9, 1977.
8. Labib KB, Bauer SB, **Blaivas JG**. External Sphincter Electromyography in a Comprehensive Urodynamic Evaluation. *Archives Phys Med & Rehab*, 58:521, 1977.
9. **Blaivas JG**, Labib KB, Scott RM. Urodynamic Evaluation as neurologic test of Sacral Cord Function. *Urology* 9:682, 1979.
10. **Blaivas JG**, Bhimani G, Labib KB. Vesicourethral Dysfunction in Multiple Sclerosis. *J Urol* 122:342-7, 1979.
11. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Failure of Bethanechol Denervation Supersensitivity as a Diagnostic Aid. *J Urol* 123:199, 1980.
12. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Cystometric Response to Propanetheline in Detrusor Hyperreflexia: Therapeutic Implications. *J Urol* 124:259, 1980.
13. **Blaivas JG**. Management of Bladder Dysfunction in Multiple Sclerosis. *Neurology* 30(2):12, 1980.

14. **Blaivas JG**, O'Donnell TF, Gottlieb P, Labib KB. Comprehensive Laboratory Evaluation of Erectile Dysfunction. *J Urol* 124:201,1980.
15. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia, *J Urol* 125:542-4,1981.
16. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia: A detailed EMG study. *J Urol* 125:545-8,1981.
17. **Blaivas JG**, Fisher DM. Combined Radiographic and Urodynamic Monitoring: Advances in Technique. *J Urol* 125:693-4,1981.
18. **Blaivas JG**, Zayed AAH, Labib KB. The Bulbocavernosus Reflex in *Urology*: A Prospective Study of 299 Patients. *J Urol* 126:197-9,1981.
19. **Blaivas JG**. The Neurophysiology of Micturition. *J Urol* 127:958-3,1982.
20. **Blaivas JG**, Awad SA, Bissada N, Khanna OP, Krane RJ, Wein AJ, et al. Urodynamic Procedures: Recommendations of the Urodynamic Society. 1. Procedures Which Should be Available for Routine Urologic Practice. *Neurourol Urodyn* 1:51-5,1982.
21. Sant GR, Heaney JA, Parkhurst EC, **Blaivas JG**. Obstructive Uropathy. A Potentially Serious Complication of Reconstructive Vascular Surgery. *J Urol* 129:16-2,1982.
22. Barbalias GA, **Blaivas JG**. Neurourologic Implications of the Pathologically Open Bladder Neck. *J Urol* 129:780-3,1983.
23. Zinner NR, Susset J, Coolseat BRLA, Griffiths D, Jonas U, Sterling AM, **Blaivas JG**, et al. Great Debate Resolved: The Urethral Closure Pressure Profile Should be Used For Diagnosis and Management of Female Stress Incontinence. *Neurourol Urodyn* 2:81-99,1983.
24. **Blaivas JG**, Barbalias GA. Characteristics of Neural Injury After Abdominal Perineal Resection. *J Urol* 129:84-7,1983.
25. Sant G, **Blaivas JG**, Meares EM. Hemiacidrin Irrigation in the Management of Struvite Calculi: Long Term Results. *J Urol* 130:1048-50,1983.
26. Norlen LJ, **Blaivas JG**, Gable H. Cystopathy in Patients With Severe Diabetic Nephropathy. Diabetic Nephropathy,1983.

27. **Blaivas JG.** Sphincter Electromyography. *Neurourol Urodyn* 2:269-88,1983.
28. Katz GP, **Blaivas JG.** A Diagnostic Dilemma: When Urodynamic Findings Differ From the Clinical Impression. *J Urol* 129:1170-4,1983.
29. Norlen LJ, **Blaivas JG**, Grodin W, Lundberg JM. Contractile Effect of Substance P on the Canine Urinary Bladder In Vivo. *Neurourol Urodyn*, 2:323-7,1983.
30. **Blaivas JG**, Barbalias GA. Detrusor External Sphincter Dyssynergia in Men With Multiple Sclerosis: An Ominous Urological Condition. *J Urol* 131:91-4,1984.
31. Barbalias GA, **Blaivas JG**, Klauber G. Critical Evaluation of the Crede Maneuver: A Urodynamic Study of 207 Patients. *J Urol* 131:91-4,1984.
32. **Blaivas JG.** Multichannel Urodynamic Studies. *Urology* 23:421-38,1984.
33. Sawczuk I, **Blaivas JG.** Successful Surgical Treatment of Giggle Incontinence. *Neurourol Urodyn* 3:63,1984.
34. **Blaivas JG.** Urodynamic Diagnosis of Primary Bladder Neck Obstruction. *World J Urol* 2:191,1984.
35. Oliver LM, **Blaivas JG**, McGuire E, Susset, J. Functional Vaginal Electrical Stimulation (FVES) for the Treatment of Frequency and Incontinence in Women. Proceedings of the Urodynamic Society, p47,1984.
36. **Blaivas JG**, Salinas J. Type III Stress Urinary Incontinence: The Importance of Proper Diagnosis and Treatment. *Surgical Forum* 35:472,1984.
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### **Books**

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2. Problems in Urology: Neurourology and Its Role in Urologic Disease: Part I, **Blaivas JG**, Chancellor MB, Guest Editors, Paulson Editor-in-Chief. 6:4,1992.
3. *Practical Neurourology: Genitourinary Complications in Neurourologic Disease*, Edited by **Blaivas JG**, Chancellor MB. Butterworth-Heineman, Boston, 1995.
4. *Topics in Clinical Urology: Evaluation and Treatment of Urinary Incontinence*, Edited by **Blaivas JG**. Igaku-Shoin. New York,1996.
5. **Blaivas JG**, Chancellor MB (eds.). *Atlas of Urodynamics*, Williams and Wilkins, 1996.
6. **Blaivas JG**. *Conquering Bladder and Prostate Problems: an Authoritative Guide for Men and Women*, Plenum Publishing Corp. New York, 1998.
7. **Blaivas JG**, Lepor H, Nitti VW, Weiss JP. *Case Studies in Benign Prostatic Hyperplasia*, Isis Medical Media Ltd. 2000.
8. Flisser AJ, Weiss JP, **Blaivas JG**. Fast Facts in Neurourology and Urodynamics, In: *Urology Highlights* 2001-02, Shah J, Editor, Health Press, Ltd, Oxford, UK,
9. **Blaivas JG**, Chancellor MB, Verhaaren MR, Weiss JP (eds.). *Atlas of Urodynamics (2<sup>nd</sup> Ed.)*, Wiley-Blackwell, 2007.
10. **Blaivas JG**, Weiss JP. *Benign Prostatic Hyperplasia and Lower Urinary Tract Symptoms, an Issue of Urologic Clinics (The Clinics: Internal Medicine)*. Saunders/Elsevier Health Sciences, 2009.
11. **Blaivas, JG**, Purohit, RS, *Diagnosis and Treatment of Overactive Bladder*, Oxford University Press, New York, 2011
12. Weiss, JP, **Blaivas, JG**, van Kerrebroeck, PEV, Wein, AJ, *Nocturia: Causes, Consequences and*

Clinical Approaches, Springer, New York, 2012

**VISITING PROFESSOR AND NAMED LECTURESHIPS**

1. Universitas Complutensas (Madrid)
2. Scandinavian Association of Urology, 1984
3. Sociedad Chilena de Urologia, 1985
4. University of Washington
5. University of Texas (Dallas), 1990
6. Tufts University, Kamil B. Labib Memorial Lecture
7. University of Iowa
8. University of Pennsylvania, 2000
9. University of Massachusetts, Harold M. Lieberman Memorial Lecture
10. Loyola University, Roland R. Cross Visiting Professor of Urology, 1992
11. Northeastern Section of the American Urologic Section, George F. Slotkin Lectureship, 2000
12. Beth Israel Medical Center (New York)
13. Case Western Reserve University, 2001
14. University of Alabama
15. Mayo Clinic (Jacksonville)
16. Albany Medical College, 2001
17. University of Toronto, 2003
18. Canadian Urologic Association
19. University of Cincinnati, 2004
20. University of Massachusetts, 2004
  
21. University of Buffalo, 2004.
22. Hugh Hampton Young lecture, Mid-Atlantic Section, AUA, 2005
23. University of Vermont 2012

**Jerry G. Blaivas, MD, FACS**  
**Biographical Sketch**

Dr. Blaivas is an internationally renowned urologist with over thirty years of clinical experience. He is, as well, an acclaimed academician, educator, writer and editor with an unimpeachable reputation for honesty and compassion. His clinical expertise ranges from office urology to the most complicated and difficult surgical problems. Known as a “doctor’s doctor,” he is considered the “doctor of last resort” by patients and doctors alike when they experience multiple failed treatments.

Dr. Blaivas is Clinical Professor of Urology at Weill Cornell Medical College, Adjunct Professor at SUNY Downstate and Attending Surgeon at New York Presbyterian Hospital and Lenox Hill Hospital. He is former Professor of Urology and Vice Chairman of the Department of Urology at Columbia University College of Physicians and Surgeons.

In addition to a widely acclaimed expertise in routine urologic conditions such as prostate problems in men, pelvic organ prolapse (dropped bladder) in women and incontinence in both sexes, Dr. Blaivas was one of the originators of urodynamics and pioneered many of the current surgical procedures to correct stress incontinence, urinary fistulas, urethral diverticulum, overactive bladder and neurogenic bladder. He is one of the few surgeons who routinely performs reconstructive surgery for prolapse and incontinence without the use of mesh and has published one of the largest series in the world on treatment of mesh complications. He has a particular interest and expertise in complex urologic problems – complications of radiation and prostate surgery, failed incontinence surgery and failed prolapse surgery.

Dr. Blaivas is former President of the Urodynamics Society and the recipient of numerous awards, including the Lifetime Achievement Award from the Society for Urodynamics and Female Urology, the Victor A. Politano Award from the American Urological Association, the F. Brantley Scott M.D. Award from the American Foundation for Urologic Disease, the J. Marion Sims Award from the American Uro-Gynecologic Society and the Paul Zimskind Award from the Urodynamic Society.

In addition, Dr. Blaivas has consistently been listed in *New York Magazine’s Best Doctors* and *Castle Connolly’s America’s Top Doctors* and *Top Doctors: New York Metro Area* from the publications’ inception in 1992 to the present.

Dr. Blaivas is the Founder of the major scientific journal *Neurourology & Urodynamics* and was Editor-in-Chief from 1982-2006. He is on the editorial board of *Contemporary Urology* and *International Urogynecology Journal* and is a reviewer for a number of other journals, including the *Journal of Urology*, *Urology*, *The New England Journal of Medicine*, and *British Journal of Urology*. He is the primary author of over 400 peer review scientific articles, book chapters and reviews and has edited seven books. He is a member of numerous professional societies, including the American Association of Genitourinary Surgeons, Society of Pelvic Surgeons, American Urological Association, American College of Surgeons, Society for Urodynamics and Female Urology, American Urogynecologic Society, and the International Continence Society.

Dr. Blaivas founded the not-for-profit organization, the Institute for Bladder and Prostate Research, which is dedicated to research relating to the lower urinary tract and female genital tract, including urinary incontinence, prostate conditions, neurogenic bladder, interstitial cystitis and genital prolapse. In addition, he is the author of a book for the lay public on bladder and prostate conditions entitled, *Conquering Bladder and Prostate Problems; an Authoritative Guide for Men and Women*.

# Exhibit B

**Jerry G. Blaivas, MD, FACS**

Urology  
445 East 77th Street  
New York, NY 10075

Diplomat  
American Board of Urology

Phone (212) 772-3900  
Fax (212) 772-1919

November 1, 2012

Margaret M. Thompson, MD JD MPAFF  
Mueller Law  
404 W. 7th Street  
Austin, TX 78701

Re: Dr. Blaivas' fee schedule

To whom it may concern:

Per your request, I have set forth Dr. Blaivas' fee schedule below. Please be advised that **fees are required prior to or at the time of service.**

\$750 per hour for review of medical records and preparation of reports.

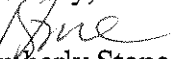
\$7,500 for a half day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

\$15,000 for a full day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

Given the nature of Dr. Blaivas' practice, he must be notified well in advance of any cancellation. Otherwise the above fee schedule will apply.

Please confirm your agreement to the above terms by signing below.

Sincerely,

  
Kimberly Stone

---

Addressee    *Sign*

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Addressee    *Print*

# Exhibit C

Document Date	Title	Primary Author	Publication
2013-00-00	Correction: Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse		N ENGL J MED 368;4:394
2012-00-00	GUIDE TO LEARNING IN FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY		
	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center Study	Abbot, et al	Presentation Number: Paper 29
2014-01-01	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Abbott, et al	Am J Obstet Gynecol 2014;210:163.e1-8
2011-01-01	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	Abdel-Fattah, et al	European Urology 60 (2011) 468 - 480
2006-01-01	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure	Abdel-Fattah, et al	BJU Int, 98(3), 594-598
2008-01-01	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	Abdel-Fattah, et al	BJOG 2008;115:22–30
	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Abdel-fattah, et al	Poster 18
2010-01-01	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes	Abdel-fattah, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111
2010-04-12	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	Abdel-fattah, et al	BJOG 2010;117:870—878

2010-05-18	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Abdelwahab, et al	Current Urology, 4(2), 93-98
2011-01-01	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Abed, et al	Int Urogynecol J (2011) 22:789–798
2011-01-01	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	Aboseif, et al	World J Urol (2011) 29:249–253
2011-00-00	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Aboushwareb, et al	Neurourology and Urodynamics 30:775--782 (2011j)
2009-01-01	Tissue mechanics, animal models, and pelvic organ prolapse: A review	Abramowitch, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 144S (2009) S146–S158
2011-01-01	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	Abrams, et al	European Urology 60:1207-1211
2006-12-01	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG	ACOG Committee Opinion No. 352
2007-02-01	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	ACOG	The American College of Obstetrics & Gynecology
2007-09-01	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN - GYNECOLOGISTS NUMBER 85	ACOG	The American College of Obstetricians and Gynecologists
2005-06-01	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Acog Committee on Practice Bulletins--Gynecology	Obstet Gynecol
2008-10-01	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	Agarwala N	UroToday International Journal / Vol 1 / Iss 4/
2007-01-01	Laparoscopic sacral colpopexy with Gynemesh as graft material-Experience and results	Agarwala, et al	Journal of Minimally Invasive Gynecology (2007) 14, 577–583

2014-01-01	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Agnew, et al	Int Urogynecol J (2014) 25:235–239
2006-00-00	Mesh migration following repair of inguinal hernia: a case report and review of literature	Agrawal, Avill	Hernia (2006) 10: 79--82
2011-01-01	Long term patient satisfaction after suburethral sling operation for stress incontinence	Al-Omary, Atalla	Int Urogynecol J (2011) 22 (Suppl 3):
2007-01-01	Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence	Albo, et al	N Engl J Med 2007;356:2143-55
2012-12-01	Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months	Albo, et al	J Urol Vol. 188, 2281-2287
2009-00-00	Isolation of fibroblasts for coating of meshes for reconstructive surgery: differences between mesh types	Albrich, et al	Regenerative Medicine
2003-01-02	Use of Cadaveric Fascia Lata To Correct Grade IV Cystocele	Almeida,et al	International Braz J Urol Vol. 29 (1): 48-52
2011-01-01	Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse	Altman, et al	N Engl J Med 2011;364:1826-36
2007-02-01	Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair	Altman, et al	Obstet Gynecol 2007;109:303–8
	INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRAPHY	Altman, et al	Abstract
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2009-01-01	Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter deficiency	Arunkalaivanan,et al	Presentation 778
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2011-12-01	Committee Opinion Number 513: Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse	Committee on Gynecologic Practice	OBSTETRICS & GYNECOLOGY Vol. 118, No. 6
2015-07-21	Long-term efficacy of the trans-obturator and retropubic mid-urethral slings	Constantini, et al	World J Urol
2004-01-01	Polypropylene in the intra-abdominal position: Influence of pore size and surface area	Conze, et al	Hernia (2004) 8: 365—372
	Randomized clinical trial comparing lightweight composite mesh with polyester or polypropylene mesh for incisional hernia repair	Conze, et al	
2008-06-01	A Historical Perspective on Cystocele Repair-From Honey to Pessaries to Anterior Colporrhaphy: Lessons from the past	Cooke, Gousse	J Urol Vol. 179, 2126-2130
2012-06-26	TVT SECUR Single-Incision Sling After 5 Years of Follow-Up: The Promises Made and the Promises Broken	Cornu, et al	European Urology 62 (2012) 735 - 738
2008-03-18	Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy	Corona, et al	Journal of Minimally Invasive Gynecology (2008) 15, 262–267
2009-09-02	Anatomy of Pelvic Floor Dysfunction	Corton M	Obstet Gynecol Clin N Am 36 (2009) 401–419
2013-01-01	Critical Anatomic Concepts for Safe Surgical Mesh	Corton, Marlene	CLINICAL OBSTETRICS AND GYNECOLOGY Volume 56, Number 2, 247–256
2014-10-23	Mini-slings can cause complications	Coskun, et al	International Urogynecology Journal
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	TRANS-VAGINAL MESH TECHNIQUE FOR TREATMENT OF PELVIC ORGAN PROLAPSE: 5 YEARS OF PROSPECTIVE FOLLOW UP	Cosson, et al	Poster
2003-07-25	Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women which is the ideal material?	Cosson, et al	Int Urogynecol J (2003) 14: 169–178
2010-04-13	Comparisons of safety and efficacy of the Obtryx® Sling and Advantage™ MidUrethral Sling for the treatment of stress urinary incontinence: Propensity matching results in a large international registry	Costa, et al	Boston Scientific Marketing
2004-00-00	Surgical Treatment of Female Stress Urinary Incontinence with a Trans-Obturator-Tape (T.O.T.) Uratape: Short Term Results of a Prospective Multicentric Study	Costa, et al	European Urology 46 (2004) 102--107
2005-04-25	Uterus Preservation in Surgical Correction of Urogenital Prolapse	Costantini, et al	European Urology 48 (2005) 642–649
2013-01-01	Surgical management of female SUI: is there a gold standard?	Cox, et al	Nat. Rev. Urol.
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2012-00-00	Evaluation of Current Biologic Meshes in Pelvic Organ Prolapse Repair	Cox, Herschorn	Curr Urol Rep (2012) 13:247--255
	Sympton Resolution After Operative management of Complications From Vaginal Mesh	Crosby, et al	Presentation Number: Paper 30
2014-01-01	Symptom Resolution After Operative Management of Complications From Transvaginal Mesh	Crosby, et al	Obstet Gynecol 2014;123:134–9
2012-01-01	Nonsurgical Management of Pelvic Organ Prolapse	Culligan PJ	Obstet Gynecol
2003-01-01	Bacterial colony counts during vaginal surgery	Culligan, et al	Infect Dis Obstet Gynecol 2003;11:161—165
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2008-01-01	Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials	Daneshgari, et al	J Urol Vol. 180, 1890-1897
2014-05-18	Postoperative pain outcomes after transvaginal mesh revision	Danford, et al	J Urol Vol. 191, No. 4S, Supplement, Sunday, May 18, 2014
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2006-05-12	Introduction to the 2005 IUGA Grafts Roundtable	Davila GW	International Urogynecology Journal 2006
2006-00-00	Multicenter experience with the Monarc transobturator sling system to treat stress urinary incontinence	Davila, et al	Int Urogynecol J (2006) 17: 460--465
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2011-01-01	The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial	de Laval, et al	Int Urogynecol J (2011) 22:145—156
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2002-01-01	Chronic pain after laparoscopic and open mesh repair of groin hernia	Kumar, et al	Br J Surg 2002, 89, 1476-1479
2010-05-01	Pelvic Organ Prolapse	Kuncharapu, et al	Am Fam Physician. 2010;81(9):1111-1117, 1119-1120
2001-00-00	Comparison of Video Urodynamic Results After the Pubovaginal Sling Procedure Using Rectus Fascia And Polypropylene Mesh for Stress Urinary Incontinence	Kuo H	J Urol 165, 163-168
2002-01-01	A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure	Kuuva and Nilsson	Acta Obstet Gynecol Scand 2002; 81: 72–77
2008-01-01	Diagnostic Criteria for Pudendal Neuralgia by Pudendal Nerve Entrapment	Labat, et al	Neurourology and Urodynamics Neurourology and Urodynamics 27:306–310

2013-09-19	Surgery versus Physiotherapy for Stress Urinary Incontinence	Labrie, et al	N Engl J Med
1988-01-01	The Value of Simultaneous Hysterectomy During Burch Colposuspension for Urinary Stress Incontinence	Langer, et al	Obstet Gynecol
2007-01-01	Levator Ani Trigger Point Injections: An Underutilized Treatment for Chronic Pelvic Pain	Langford, et al	Neurourology and Urodynamics 26:59^62 (2007)
2005-00-00	Open retropubic colposuspension for urinary incontinence in women (Review)	Lapitan, et al	The Cochrane Library
2009-01-01	Open Retropubic Colposuspension for Urinary Incontinence in Women: A Short Version Cochrane Review	Lapitan, et al	Neurology and Urodynamics
2014-01-01	Outcomes of trocar-guided Gynemesh PS™ versus single-incision trocarless Polyform™ transvaginal mesh procedures	Larouche, et al	Int Urogynecol J
1995-00-00	MACROPHAGES AND INFLAMMATORY MEDIATORS IN TISSUE INJURY	Laskin, Pendino	Annu Rev Pharma Toxicol 35:655-77
2007-03-16	Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications	Latthe, et al	BJOG 2007;114:522—531
2006-01-01	WHO systematic review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity	Latthe,et al	BMC Public Health
2011-01-26	Comparing effectiveness of combined transobturator tension-free vaginal mesh(Perigee) and transobturator tension-free vaginal tape(TVT-O) versus anterior colporrhaphy and TVT-O for associated cystocele and urodynamic stress incontinence	Lau, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 156 (2011) 228–232
2007-01-01	Retropubic Compared With Transobturator Tape Placement in Treatment of Urinary Incontinence: A Randomized Controlled Trial	Laurikainen, et al	Obstet Gynecol 2007;109:4—11
1997-09-01	FEMALE STRESS URINARY INCONTINENCE CLINICAL GUIDELINES PANEL SUMMARY REPORT ON SURGICAL MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE	Leach, et al	J Urol Vol. 158, 875-880
2012-06-22	Which women develop urgency or urgency urinary incontinence following midurethral slings?	Lee, et al	Int Urogynecol J

2013-01-01	Transvaginal Mesh Kits-How Serious are the complications and are they reversible	Lee, et al	UROLOGY 81: 43-49
2012-07-01	Native tissue repairs in anterior vaginal prolapse surgery: examining definitions of surgical success in the mesh era	Lee, et al	Curr Opin Urol 2012, 22:265–270
2007-10-17	Prospective comparison of the 'inside —out' and 'outside —in' transobturator-tape procedures for the treatment of female stress urinary incontinence	Lee, et al	Int Urogynecol J (2008) 19:577—582
2007-01-01	A Prospective Trial Comparing Tension-Free Vaginal Tape and Transobturator Vaginal Tape Inside-Out for the Surgical Treatment of Female Stress Urinary Incontinence: 1-Year Followup	Lee, et al	J Urol Vol. 177, 214-218
2013-01-01	Long-Term Outcomes of Autologous Pubovaginal Fascia Slings: Is There a Difference Between Primary and Secondary Slings?	Lee, et al	Neurourology and Urodynamics
2014-01-01	Mesholgy: a fast growing field involving mesh and or tape removal procedures and their outcomes	Lee, et al	Informa doi: UK10.1586/17434440.2015.985655
2015-00-00	Long-term Outcomes of Autologous Pubovaginal Fascia Slings	Lee, et al	Neurourology and Urodynamics 34:18--23 (2015)
1995-04-01	Osteitis Pubis: A Review	Lentz, Samuel S.	Obstetrical & Gynecological Survey
	COMPARISON OF SURGICAL OUTCOMES AFTER AUGMENTED ANTERIOR/APICAL REPAIR USING TWO DIFFERENT MATERIALS: DERMAL GRAFT AND POLYPROPYLENE MESH.	Letko, et al	Abstract
	Ultrasound Evaluation of Polypropylene Mesh Contraction at Long Term after Vaginal Surgery for Cystocele Repair	Letouzey, et al	Abstracts / Journal of Minimally Invasive Gynecology 16 (2009) S1—S51
2012-01-01	Is polypropylene mesh coated with antibiotics efficient to prevent mesh infection and contraction in an animal infectious model?	Letouzey, et al	Int Urogynecol J (2012) 23 (Suppl 2):S43—S244
2011-01-01	Ultrasonographic Scan Evaluation of Synthetic Mesh Used for vaginal cystocele repair	Letouzey, et al	Journal of Minimally Invasive Gynecology 18 (2011) S47–S70

2011-01-01	Ultrasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arms Trans Obturator Techniques to Bilateral Anterior Sacrospinous Ligament and Arcus Tendineus Suspension At 1 Year Follow Up	Letouzey, et al	Int Urogynecol J (2011) 22 (Suppl 1):SI - S195
2010-01-01	Ultrasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arms Trans Obturator Techniques to Anterior Bilateral Sacro Spinous Ligament and Arcus Tendinous Suspension	Letouzey, et al	ICS-IUGA 2010 Abstract 43
	Vaginal degeneration following implantation of synthetic mesh with increased stiffness	Liang, et al	
2012-00-00	Sexual function in women following transvaginal mesh procedures for the treatment of pelvic organ prolapse	Liang, et al	Int Urogynecol J. 2012 Oct;23(10):1455-60
2007-08-01	Monarc vs TVT-O for the treatment of primary stress incontinence: a randomized study	Liapis, et al	Int Urogynecol J (2008) 19:185—190
2009-01-01	Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up	Liapis, et al	European Journal of Obstetrics Ih Gynecology and Reproductive Biology 148 (2010) 199-201
2006-05-16	Tension-free vaginal tape versus tension-free vaginal tape obturator in women with stress urinary incontinence	Liapis, et al	Gynecoi Obstet Invest 2006;62 I60i 164
2002-01-01	Burch Colposuspension and Tension-Free Vaginal Tape in the Management of Stress Urinary Incontinence in Women	Liapis, et al	European Urology
2005-01-01	Suburethral slingplasty evaluation study in North Queensland, Australia: The SUSPEND trial	Lim, et al	Australian and New Zealand Journal of Obstetrics and Gynaecology 2005; 45: 52–59
2006-00-00	Clinical and quality-of-life outcomes in women treated by the TVT-O procedure	Lim, et al	BLOG 2006;113:1315--1320.
2010-05-04	Do the Advantage slings work as well as the tension-free vaginal tapes?	Lim, et al	Int Urogynecol J (2010) 21:1157-1162
2007-01-01	Dyspareunia and chronic pelvic pain after polypropylene mesh augmentation for transvaginal repair of anterior vaginal wall prolapse	Lin, et al	Int Urogynecol J (2007) 18:675–678

2005-03-01	IN VIVO TENSION SUSTAINED BY FASCIAL SLING IN PUBOVAGINAL	Lin, et al	J Urol Vol. 173, 894-897
2010-10-01	Polypropylene mesh used for adjuvant reconstructive surgical treatment of advanced pelvic organ prolapse	Lin, et al	J. Obstet. Gynaecol. Res. Vol. 36, No. 5: 1059-1063
2015-00-00	A first reported case of clear cell carcinoma associated with delayed extrusion of midurethral tape	Lin, et al	Int Urogynecol J DOI 10.1007/s00192-015-2876-5
2007-03-29	PrePubic Mid-Urethral Sling for Stress Urinary Incontinence: Prospective Single-Arm Clinical Study of Efficacy, Safety and Sexual Function - Interim Data	Lind, et al	
2011-01-01	Neurophysiological characterization of persistent pain after laparoscopic inguinal hernia repair	Linderroth, et al	Hernia, 15(5), 521-529
2009-04-01	The Rapid Evolution of Vaginal Mesh Delivery Systems for the Correction of Pelvic Organ Prolapse:Part 1	Littman, Culligan	Female Patient VOL 34, 2-8
2009-05-01	The Rapid Evolution of Vaginal Mesh Delivery Systems for the Correction of Pelvic Organ Prolapse: Part 2	Littman, Culligan	The Female Patient Vol 34, 1-2
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2009-10-01	Long Term Efficacy And Safety Of The Obtryx (Boston Scientific Corp.) Sling For Treatment Of Stress Urinary Incontinence In A Community Setting: An Analysis Of Outcomes And Quality Of Life	Litwiller, et al	Journal of Pelvic Medicine & Surgery 12, 5
2009-03-04	Combined Pelvic Reconstructive Surgery and Transobturator Tape (Monarc) in Women with Advanced Prolapse and Urodynamic Stress Incontinence: A Case Control Series	Lo TS	Journal of Minimally Invasive Gynecology (2009) 16, 163-166
2014-11-06	Sacrospinous Ligament Fixation of Transvaginal Mesh: An innovative concept 10 years influence	Lo TS	Gynecology and Minimally Invasive Therapy
2012-00-00	Scarless Fetal Skin Wound Healing Update	Lo, et al	Birth Defects Research (Part C) 96:237-247
2012-01-07	Risk factors of surgical failure following transvaginal mesh repair for the treatment of pelvic organ prolapse	Long, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 161 (2012) 224–227
2012-01-01	Changes in Female Sexual Function following Anterior with and without Posterior Vaginal Mesh Surgery for the Treatment of pelvic Organ Prolapse	Long, et al	J Sex Med 2012;9:2167–2174

2010-09-10	Comparison of clinical outcome and urodynamic findings using "Perigee and/or Apogee" versus "Prolift anterior and/or posterior" system devices for the treatment of pelvic organ prolapse	Long, et al	Int Urogynecol J (2011) 22:233–239
2005-01-01	Mesh repair of parastomal hernias - a safety modification	Longman, Thomson	Colorectal Disease, 7, 292—294
2010-01-01	Transvaginal polypropylene mesh versus sacrospinous ligament fixation for the treatment of uterine prolapse 1-year follow-up of a randomized controlled trial	Lopes, et al	International Urogynecology Journal 21: 389-394
2006-00-00	A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence	Lord, et al	BJU Int 98, 367-76
2002-01-01	Safety and Efficacy of Sacrospinous Vault Suspension	Lovatsis, Drutz	Int Urogynecol J (2002) 13:308–313
2013-01-01	Colpocleisis: Current Practice and Complications	Lowenstein, Erisson	Complications of Female Incontinence and Pelvic Reconstructive Surgery
2006-01-27	Neural pain after uterosacral ligament vaginal suspension	Lowenstein, et al	Int Urogynecol J (2007) 18: 109–110
	Small-pore polypropylene slings: still out there	Lowery, et al	
2012-01-01	EAU Guidelines on Surgical Treatment of Urinary Incontinence	Lucas, et al	European Urology 62 (2012) 1118—1129
2003-02-00	Laparoscopic Burch colposuspension for stress urinary incontinence: When, how, and why'?	Lucente, Murphy	OBG MANAGEMENT
2005-01-01	Suture erosion and wound dehiscence with permanent versus absorbable suture in reconstructive posterior vaginal surgery	Luck, et al	Am J Obstet Gynecol
2003-01-01	The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation	Lukacz,et al	Int Urogynecol J
2009-01-01	Polypropylene mesh vs. site-specific repair in the treatment of anterior vaginal wall prolapse: preliminary results of a randomized clinical trial	Lundardelli, et al	Rev. Col. Bras. Cir. 2009; 36(3): 210-216

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	The outcome of transobturator cystocele repair using biocompatible porcine dermis graft: our experience with 32 cases	Mahdy, et al	
2006-01-01	Surgical management of anterior vaginal wall prolapse an evidencebased literature review	Maher, Baessler	Int Urogynecol J (2006) 17: 195–201
2010-01-01	Surgical management of pelvic organ prolapse in women review	Maher, et al	The Cochrane Library 2010, Issue 8
2011-04-01	Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial	Maher, et al	Am J Obstet Gynecol 2011;204:360.e1-7
2008-01-01	Surgical Management of Pelvic Organ Prolapse in Women: A Short Version Cochrane Review	Maher, et al	Neurourology and Urodynamics 27:3–12 (2008)
2013-01-01	Surgical management of pelvic organ prolapse in women	Maher, et al	The Cochrane Library 2013, Issue 4
2013-09-01	The transvaginal mesh decade	Maher, Haya	Expert Review of Obstetrics & Gynecology. 8.5 (Sept. 2013): p 485
2015-05-00	The Foreign Body Response: At the Interface of Surgery and Bioengineering	Major, et al	Plast. Reconstr. Surg. 135: 1489, 2015.
2012-10-10	Graft-related complications and biaxial tensiometry following experimental vaginal implantation of flat mesh of variable dimensions	Manodoro,et al	BJOG 2013;120:244–250
2012-01-01	Persistent pelvic pain following transvaginal mesh surgery: a cause for mesh removal	Marcus-Braun, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 162 (2012) 224–228
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	The Micorbiota of the Vagina and Its Influence on Women's Health and Disease	Martin DH	

2011-01-01	RANDOMIZED PROSPECTIVE TRIAL OF A COMPARISON OF THE EFFICACY OF TVT-O AND TVT SECUR SYSTEM IN THE TREATMENT OF STRESS URINARY INCONTINENT WOMEN – COMPARISON OF THE LONG- AND SHORT-TERM RESULTS	Masata, et al	ICS 2011
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2012-01-01	Outcome of Obtryx transobturator sling for stress incontinence in Scottish women	May, et al	Poster 429
2015-03-24	Mechanical biocompatibility of highly deformable biomedical materials	Mazza, Ehret	Journal of the Mechanical Behavior of Biomedical Materials
2016-02-01		McCammon and Kobashi	The Journal of Urology
2010-01-01	An update on surgery for pelvic organ prolapse	McIntyre, et al	Curr Opin Urol 20:490–494
1981-01-01	From "Promising Report" to "Standard Procedure": Seven Stages in the Career of a Medical Innovation	McKinlay J	Seven Stages in the Career of a Medical Innovation
2005-00-00	Bladder Perforation During Tension-Free Vaginal Tape Procedures Analysis of Learning Curve and Risk Factors	McLennn, Melick	Obstet Gynecol 2005;106:1000-4
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2011-00-00	Late urethral erosion of transobturator suburethral mesh (Obtape): a minimally invasive management under local anaesthesia	Mendonca, et al	Int Urogynecol J (2011) 22:37--39
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1989-00-00	In vivo and in vitro degradation of monofilament absorbable sutures, PDS and Maxon	Metz, et al	Biomaterials, 11(1), 41-45
2006-01-01	Hydrogen peroxide producing lactobacilli in women with vaginal infections	Mijac, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 129 (2006) 69–76
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2005-01-01	Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh	Milani, et al	BJOG Vol. 112, pp. 107-111
2011-01-01	Sexual Function Following Trocar-guided Mesh or Vaginal Native Tissue Repair in Recurrent Prolapse: A Randomized Controlled Trial	Milani, et al	J Sex Med 2011;8:2944–2953
2009-01-01	International Urogynecological Association- Short Term Outcomes and Peri-Operative Events after a new transvaginal anterior and apical mesh repair	Miller D	International Urogynecological Association
	Prospective Clinical Assessment of the Transvaginal Mesh Technique for Treatment of Pelvic Organ Prolapse—5-Year Results	Miller, et al	AUG S CONFERENCE PRESENTATION
2012-00-00	Informed surgical consent for a mesh/graft-augmented vaginal repair of pelvic organ prolapse	Miller, et al	Int Urogynecol J
2008-00-00	Pathology of ilioinguinal neuropathy produced by mesh entrapment: case report and literature review	Miller, et al	Hernia (2008) 12:213--216
2009-01-01	COMPARISON OF TRANSVAGINAL ANTERIOR MESH SYSTEMS FOR SUPPORT OF ANTERIOR AND APICAL COMPARTMENTS IN A CADAVER MODEL	Miller, Lotze	Journal of Pelvic Medicine & Surgery · Volume 15, Number 2 ,
2009-01-01	Comparison of Transvaginal Mesh System Placement for Support of Anterior and Apical Compartments in a Cadaver Model	Miller, Lotze	Int Urogynecol J (2009) 20 (Suppl 2):S99-S100
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2014-03-11	Poypropylene mesh: evidence for lack of carcinogenicity	Moalli, et al	Int Urogynecol J (2014) 25:573–576
2012-00-00	FEASIBILITY AND SHORT-TERM OUTCOMES FOLLOWING THE USE OF THE UPHOLD VAGINAL SUPPORT SYSTEM FOR TREATMENT OF SYMPTOMATIC VAGINAL	Mobley, et al	Neurourology and Urodynamics DOI 10.1002
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2007-01-18	Vaginal pressure during daily activities before and after vaginal repair	Mouritsen, et al	Int Urogynecol J (2007) 18:943–948
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2010-01-01	Use of vaginal mesh in the face of recent FDA warnings and litigation	Mucowski, et al	Am J Obstet Gynecol 2010;203:103.e1-4
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	Transvaginal Sling Release With Intraoperative Ultrasound Guidance	Mukati, Shobeiri	
2010-01-01	Urethral strictures	Mundy, Andrich	BJUI
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	Use of Mesh and Materials in Pelvic Floor Surgery	Murphy M	Obstet Gynecol Clin N Am 36 (2009) 615–635
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2013-01-01	Complications of Anterior Compartment Repair	Murphy, Moore	Complications of Female Incontinence and Pelvic Reconstructive Surgery
2011-01-01	Mesh kits for anterior vaginal prolapse are not cost effective	Murray, et al	Int Urogynecol J (2011) 22:447–452
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	Stress urinary incontinence in women Retropubic midurethral slings	Nager, et al	
	Transobturator tape for stress incontinence: The North Queensland experience	Naidu, et al	
2014-01-01	Single-incision sling operations for urinary incontinence in women (Review)	Nambiar, et al	The Cochran Collaboration
2014-01-01	Single-incision sling operations for urinary incontinence in women (Review) Complete	Nambiar, et al	The Cochrane Library
2007-01-01	The role of local vaginal estrogen for treatment of vaginal atrophy in postmenopausal women: 2007 position statement of The North American Menopause Society	NAMS The Board of Trustees of the North American Menopause Society	Menopause: The Journal of the North American Menopause Society
2006-00-00	Pelvic floor reconstructive surgery: which aspects remain controversial?	Natale, Franca	Curr Opin Urol 16:407-412.
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2008-06-01	Surgical repair of vaginal wall prolapse using mesh	National Institute for Health and Clinical Excellence	National Institute for Health and Clinical Excellence
2008-00-00	Outcome After Anterior Vaginal prolapse repair: A Randomized Controlled Trial	Nguyen, Burchette	Obstet Gynecol 2008;111:891–8
2012-03-01	Perioperative Complications and reoperations after incontinence and prolapse surgeries using prosthetic implants	Nguyen, et al	Obstet Gynecol 2012;119:539–46
2010-03-30	Update: Answer to some common questions	NICE	

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1998-09-00	A New Operation for Genitourinary Prolapse	Nicita G	J Urol 160, 741 - 745
2010-09-01	Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow up	Nieminen, et al	Am J Obstet Gynecol 2010;203:235.e1-8
2008-01-01	Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh	Nieminen, et al	Int Urogynecol J (2008) 19:1611–1616
2015-01-01	Creating a gold standard surgical procedure	Nilsson, CG	Int Urogynecol J
2013-04-06	Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence	Nilsson, et al	Int Urogynecol J (2013) 24:1265-1269
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2013-01-01	Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience From a Referral Center	Smith, et al	Female Pelvic Med Reconstr Surg 2013;19: 238-241
2011-01-01	Single-incision Midurethral tape (Ophira) vs. Transobturator tape (Obtryx): Prospective comparative study at a median follow-up of 6 months	Smith, et al	IUGA Poster
2013-08-01	Comparison of single-incision mid-urethral tape (Ophira) and transobturator tap (Obtryx) suburethral sling procedures for female stress urinary incontinence	Smith, et al	Journal of Clinical Medicine and Research
2011-07-25	Society of Gynecologic Surgeons (SGS) Executive Committee Statement Regarding the FDA Communication	Society of Gynecologic Surgeons (SGS) Executive Committee	
2012-01-01	One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse	Sokol, et al	Am J Obstet Gynecol 2012;206:86.e1-9
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2007-00-00	Low Erosion Rate With Posterior Repair Utilizing a Polypropylene Mesh-kit Through a Transverse Introital Incision	Sprock MJ	Journal of Minimally Invasive Gynecology, Vol 14, No 6, November/December Supplement 2007
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	A Comprehensive Review of Suburethral Sling Procedure Complications	Stanford, Paraiso	
1999-01-14	Nerve irritation after laparoscopic hernia repair	Stark, et al	Surg Endosc (1999) 13: 878–881
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2012-01-01	Urinary bladder stones in women	Stav, Dwyer	OBSTETRICAL AND GYNECOLOGICAL SURVEY, 67; 11: 715 - 725
2009-01-01	Pudendal Neuralgia Fact or Fiction	Stav, et al	Volume 64, Number 3 OBSTETRICAL AND GYNECOLOGICAL SURVEY
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2009-01-01	Evaluation and Treatment of Dyspareunia	Steege, Zolnoun	Obstet Gynecol 2009;113:1124–36
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	One-Year Anatomic and Quality of Life Outcomes Following the Anterior Pinnacle Lift Kit Procedure for the Treatment of Pelvic Organ Prolapse	Steinberg, et al	Oral Poster 14
2009-01-01	Vaginal Reconstructive Surgery Using Pinnacle Mesh Kit vs Open Abdominal vs Laparoscopic Sacrocolpopexy - Comparison of Outcomes	Sternchuss, et al	Journal of Minimally Invasive Gynecology 16 (2009) S44

2012-07-01	Post-Implantation Alterations of Polypropylene in the Human	Sternschuss, et al	J Urol 188:27-32
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	The challenge of evaluating surgical procedures	Stirrat, et al	
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2007-07-00	Comparison of Retropubic vs Transobturator Approach to Midurethral Slings: a systematic review and meta-analysis	Sung, et al	American Journal of Obstetrics & Gynecology
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2004-10-14	Pelvic Organ Support Study: The distribution , clinical definition, and epidemiologic condition of pelvic organ support defects	Swift, et al	American Journal of Obstetrics and Gynecology (2005) 192, 795–806
	To Assess the Surgical Feasibility of Utilization of a Mesh Kit (Avaulta Solo Support System) in the Treatment of Pelvic Floor Prolapse	Syed R	
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	RANDOMISED TRIAL OF TVT AND TVT-O FOR THE TREATMENT OF URODYNAMIC STRESS INCONTINENCE IN WOMEN	Teo, et al	
	Repair of Groin Hernia With Synthetic Mesh: Meta-Analysis of Randomized Controlled Trials	The EU Hernia Trialists Collaboration	
	A Randomized Controlled Trial of Anterior Colporrhaphy and Perigee As a Primary Surgical Correction of Symptomatic Cystocele	Thijs, et al	Abstract
2010-01-01	ONE YEAR RESULTS OF A PROSPECTIVE RANDOMIZED TRIAL COMPARING THE ORIGINAL INSIDE-OUT TRANSOBTURATOR (TVT-O™) PROCEDURE AND A MODIFIED VERSION USING A SHORTENED TAPE AND REDUCED DISSECTION FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE	Thomas, et al	Int Urogynecol J (2010) 21 (Suppl 1):S1—S428
2011-06-17	Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh	Tijdink, et al	Int Urogynecol J (2011) 22:1395–1404
2011-12-01	The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women	Tincello, et al	J Urol Vol. 186, 2310-2315
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2012-10-01	UPHOLD VAGINAL SUPPORT SYSTEM IN THE SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE	Tipton, et al	Female Pelvic Medicine & Reconstructive Surgery • Volume 18, Number 8, Supplement 1,
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2010-01-01	Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up	Tommaselli, et al	Int Urogynecol J (2010) 21:1211—1217
2015-01-27	Medium-term and long-term outcomes following placement of midurethral slings for urinary incontinence	Tommaselli, et al	Int Urogynecol J
2009-02-04	Perineal approach to vascular anatomy during transobturator cystocele repair	Touboul, et al	BJOG 2009;116:708-712
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2014-01-01	Overview of transvaginal placement of reconstructive materials (surgical mesh or biografts) for treatment of pelvic organ prolapse or stress urinary incontinence	Trabuco, Gebhart	UpToDate
2011-08-30	Safety and Effectiveness of Transvaginal Surgical Mesh Used for Repair of Pelvic Organ Prolapse	Transvaginal mesh Industry Working Group, et al	
2014-01-01	Characteristics and temporal trends in patient registries: focus on the life sciences industry,	Travers, et al	Pharmacoepidemiology and Drug Safety
2008-00-00	Neuropathic pain, Redefinition and a grading system for clinical and research purposes	Treede, et al	Neurology 2008;70:1630-1635
2004-10-27	Randomized comparison of suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women	Tseng, et al	Int Urogynecol J (2005) 16: 230—235
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2008-03-01	Complications of Synthetic Mid-Urethral Slings	Twiss, Raz	
2014-01-01	IN-DEPTH NANO-INVESTIGATION OF VAGINAL MESH AND TAPE FIBER EXPLANTS IN WOMEN	Tzartzeva, et al	Abstract
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2013-01-01	Comparison of Contraction Exposure Rate Following Vaginal as Opposed to Abdominal Implantation of Flat-Polypropylene implant	Urbankova, et al	Int Urogynecol J (2013) 24 [Suppl1]:S1-S152
2008-01-01	The Trial of Mid-urethral slings [TOMUS]: Design and Methodology	Urinary Incontinence Treatment Network	J App Res 8,1:1-13
1989-08-01	Labeling Regulatory Requirements for Medical Devices	US Department of Health & Human Service	
2011-04-09	Use of the Gynecare Prolift system in surgery for pelvic organ prolapse: 1-year outcome	Vaiyapuri, et al	Int Urogynecol J (2011) 22:869–877
2008-01-01	TORP - Comparing the efficacy, execution and early complications of TVT and TVT-O	Valentim-Lourenco, et al	Int Urogynecol J (2008) 19 (Suppl 1):S1–S166
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2007-06-16	All oral presentations made at the 32nd Annual IUGA Meeting	Various	
2008-08-01	3-D Ultrasound Characterization of Mid-Urethral Slings: A Comparison of Three Different Sling Types	Vassallo, et al	Journal of Pelvic Medicine & Surgery Volume 14, Number 4
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2006-00-00	Nerve injury: an exceptional cause of pain after TVT	Vervest, et al	Int Urogynecol J (2006) 17: 665—667

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2012-00-00	Midurethral sling incision: indications and outcomes	Viereck, et al	Int Urogynecol J DOI 10.1007/s00192-012-1895-8
2003-12-10	The use of pessaries in vaginal prolapse	Vierhout M	European Journal of Obstetrics & Gynecology and Reproductive Biology 117 (2004) 4–9
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	Surgical Management of the Pelvis Plexus and Lower Abdominal Nerves	Viswanathan, et al	
2003-02-01	Surgical Intervention for Complications for the Tension-free Vaginal Tape Procedure	Volkmer, et al	J Urol Vol. 169, 570-574
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2004-02-25	Laparoscopic sacrocolpopexy: results of a 100-patient series with 8 years follow-up	Von Theobald, Cheret	Gynecol Surg (2004) 1:31–36
1981-00-00	Emergency Abdominal Wall Reconstruction with Polypropylene Mesh: Short-term Benefits Versus Long-term Complications	Voyles, et al	Ann Surg
2012-01-01	Minimal mesh repair for apical and anterior prolapse: initial anatomical and subjective outcomes	Vu, et al	Int Urogynecol J (2012) 23:1753-1761

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2010-01-01	A NEW 'MINIMAL MESH' ANTERIOR-APICAL REPAIR	Vu, et al	Female Pelvic Medicine & Reconstructive Surgery
2005-09-01	AUTOLOGOUS FASCIAL SLING VS POLYPROPYLENE TAPE AT SHORT-TERM FOLLOWUP: A PROSPECTIVE RANDOMIZED STUDY	Wadie, et al	J Urol Vol. 174, 990—993
	Statement by L. Lewis Wall	Wall L	
2002-00-00	Pharmaceutical Sales Representatives and the Doctor/Patient Relationship	Wall, Brown	Obstet Gynecol 2002;100: 594-9
2010-01-01	The perils of commercially driven surgical innovation	Wall, Brown	Am J Obstet Gynecol 2010;202:30.e1-4.
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2013-01-01	Surgical Treatment of Vaginal Apex Prolapse	Walters, Ridgeway	Obstet Gynecol 2013;121:354–74
2008-01-01	Editorial Comment on: Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices	Waltregny D	European Urology 53 (2008) 308-309
2006-06-01	Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup	Waltregny, et al	J Urol Vol. 175, 2191-2195
2008-11-04	The TVT-obturator surgical procedure for the treatment of female stress urinary incontinence: a clinical update	Waltregny, et al	Int Urogynecol J (2009) 20:337–348

2012-00-00	New Surgical Technique for Treatment of Stress Urinary Incontinence TVT-ABBREVO: From Development to Clinical Experience	Waltregny, et al	Surg Technol Int. 2012 Dec;22:149-57
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2002-07-13	Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence	Ward, et al	BMJ VOLUME 325
2008-00-00	Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up	Ward, KL; Hilton, P	BJOG 115, 226-33 (2008)
2000-00-00	Lower Extremity Neuropathies Associated with Lithotomy Positions	Warner, et al	Anesthesiology 2000; 93:938-42

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2009-02-01	Are new tools for correcting prolapse and incontinence better just because they're new?	Weber A	OBG Management 2; 21:e3 - e8
2011-03-01	Informed consent cannot be obtained for use of vaginal mesh	Weber A and Mucowski, et al	American Journal of Obstetrics & Gynecology e6
1995-04-01	Sexual Function in Women With Uterovaginal Prolapse and Urinary Incontinence	Weber, et al	
1995-12-01	Vaginal Anatomy and Sexual Function	Weber, et al	
2001-12-01	Anterior colporrhaphy: A randomized trial of three surgical techniques	Weber, et al	Am J Obstet Gynecol 2001;185:1299-306
2001-01-01	The Standardization of Terminology for Researchers in Female Pelvic Floor Disorders	Weber, et al	Int Urogynecol J (2001) 12:178—186
2012-01-01	A Midurethral Sling to Reduce Incontinence after Vaginal Prolapse Repair	Wei, et al	N Engl J Med 2012;366:2358-67.
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2011-12-01	Informed consent and the use of transvaginal synthetic mesh	Whiteside J	Obstet Gynecol 2011;118:1409—16
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	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Vol.74	WHO	
2010-01-01	Short-term efficacy of a tranobturator sling in women veterans with a history of sexual trauma	Wilson, et al	MAAUA 68th Annual Meeting Abstracts
2006-01-01	The use of synthetic mesh in female pelvic reconstructive surgery	Winters, et al	BJU INTERNATIONAL 98, SUPPLEMENT1,70—7 6

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2008-00-00	Histologic Comparison of Pubovaginal Sling Graft Materials: A Comparative Study	Woodruff, et al	UROLOGY 72: 85--89
2011-00-00	Central sensitization: Implications for the diagnosis and treatment of pain	Woolf C	PAIN 152 (2011) S2--S15
	Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050	Wu, et al	
2014-06-01	Lifetime Risk of Stress Urinary Incontinence or Pelvic Organ Prolapse Surgery	Wu, et al	Obstet Gynecol 2014;123:1201–6
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2004-00-00	Host response after reconstruction of abdominal wall defects with porcine dermal collagen in a rat model	Zheng, et al	American Journal of Obstetrics and Gynecology (2004) 191, 1961--70
	Value of the pudendal nerves terminal motor latency measurements in the diagnosis of occult stress urinary incontinence	Zhu, et al	
2007-01-01	Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence	Zhu, et al	International Journal of Gynecology and Obstetrics (2007) 99, 14—17
	Mesh distortion video	Zolnoun, Denniz	Video
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ETH.MESH.03923121	ETH.MESH.03923122
ETH.MESH.03928235	
ETH.MESH.03932909	ETH.MESH.03932911
ETH.MESH.03934952	ETH.MESH.03934967
ETH.MESH.03941617	ETH.MESH.03941618
ETH.MESH.04044552	
ETH.MESH.04048515	ETH.MESH.04048520
ETH.MESH.04081189	ETH.MESH.04081190
ETH.MESH.04081301	ETH.MESH.04081302
ETH.MESH.04093125	
ETH.MESH.04127238	
ETH.MESH.04982735	ETH.MESH.04982743
ETH.MESH.04982748	ETH.MESH.04982752
ETH.MESH.05125268	ETH.MESH.05125271
ETH.MESH.05222673	ETH.MESH.05222705
ETH.MESH.05225354	ETH.MESH.05225385
ETH.MESH.05342590	ETH.MESH.05342592
ETH.MESH.05588123	ETH.MESH.05588126
ETH.MESH.05644163	ETH.MESH.05644171
ETH.MESH.05799233	ETH.MESH.05799316
ETH.MESH.05815791	ETH.MESH.05815802
ETH.MESH.06040171	ETH.MESH.06040173
ETH.MESH.06696589	ETH.MESH.06696592
ETH.MESH.06860553	ETH.MESH.06860558
ETH.MESH.07192929	
ETH.MESH.07455218	ETH.MESH.07455219
ETH.MESH.07455220	ETH.MESH.07455221
ETH.MESH.07690752	ETH.MESH.07690788
ETH.MESH.08003197	ETH.MESH.08003212
ETH.MESH.08073794	ETH.MESH.08073795
ETH.MESH.08073801	ETH.MESH.08073803
ETH.MESH.08307690	ETH.MESH.08307692
ETH.MESH.08334245	
ETH.MESH.08578490	ETH.MESH.08578493
ETH.MESH.08582600	ETH.MESH.08582614
ETH.MESH.08692936	ETH.MESH.08692943
ETH.MESH.08696084	ETH.MESH.08696134
ETH.MESH.09143435	ETH.MESH.09143436
ETH.MESH.09170211	ETH.MESH.09170213
ETH.MESH.09199174	ETH.MESH.09199177
ETH.MESH.09275875	ETH.MESH.09275876

Bates range of Ethicon documents relied upon by

Dr. Blaivas for his Wave 1 sling reports

ETH.MESH.09293114	
ETH.MESH.09656790	ETH.MESH.09656795
ETH.MESH.09744866	ETH.MESH.09744867
ETH.MESH.09911296	ETH.MESH.09911299
ETH.MESH.09951087	ETH.MESH.09951090
ETH.MESH.11434264	ETH.MESH.11434272
ETH.MESH.12831391	ETH.MESH.12831404
ETH.MESH.12844215	ETH.MESH.12844218
ETH.MESH.12868401	ETH.MESH.12868450
ETH.MESH.12869193	ETH.MESH.12869194
ETH.MESH.12881753	ETH.MESH.12881760
ETH.MESH.15236825	ETH.MESH.15236833
ETH.MESH.16416002	ETH.MESH.16416004
ETH.MESH.18645133	ETH.MESH.18645524
ETH.MESH.18656464	ETH.MESH.18656972
ETH.MESH.18656973	ETH.MESH.18659066
ETH.MESH.18659067	ETH.MESH.18660346
ETH.MESH.18660347	ETH.MESH.18660992
ETH.MESH.18660993	ETH.MESH.18661580
ETH.MESH.18882038	ETH. MESH.18883404
ETH.MESH.18886712	ETH.MESH. 18887346
ETH.MESH.18887347	ETH.MESH.18887400

slings reports

Date	Description
2015-01-01	Gynecare TVT Obturator System Instructions for Use
2015-01-01	Gynecare TVT EXACT Instructions for Use
2015-01-01	Gynecare TVT ABBREVO Instructions for Use
2015-01-00	Gynecare TVT Instructions for Use
	Operation Abbrevio Video
2006-11-20	C4001 POLYPROPYLENE MSDS
2005-04-13	C4001 POLYPROPYLENE HOMOPOLYMER MSDS
2004-03-12	C4001 POLYPROPYLENE HOMOPOLYMER MSDS

Document Date	Testimony
4/5/2012	Deposition of Piet Hinoul
4/6/2012	Deposition of Piet Hinoul
9/12/2012	Deposition of Charlotte Owens
9/13/2012	Deposition of Charlotte Owens
5/22/2013	Deposition of Daniel Burkley
5/23/2013	Deposition of Daniel Burkley
5/30/2013	Deposition of Martin Weisberg
5/31/2013	Continued Videotaped Deposition 30(b)(6)of Martin Weisberg Volume II
6/20/2013	Videotaped Deposition of Christophe Vailhe
6/21/2013	Continued Videotaped Deposition of Christophe Vailhe Volume II
6/26/2013	Deposition of Piet Hinoul
6/27/2013	Deposition of Piet Hinoul
7/24/2013	Videotaped Deposition of David Brown Robinson Volume I
7/25/2013	Videotaped Deposition of David Brown Robinson Volume II
7/29/2013	Videotaped Deposition of Joerg Holste
7/30/2013	Continued Videotaped Deposition of Joerg Holste
8/9/2013	Continued Videotaped Deposition of Martin Weisberg Volume III
9/11/2013	Videotaped Deposition of Brigitte Hellhammer
9/11/2013	Videotaped Deposition of David Brown Robinson Volume III
9/11/2013	Deposition of Daniel Lamont
11/6/2013	Deposition of Richard Isenberg
1/7/2014	Videotaped Deposition of Thomas A. Barbolt
1/8/2014	Deposition of Thomas Barbolt Volume II
1/13/2014	Deposition of Piet Hinoul
2/3/2014	Deposition of Daniel Smith
2/4/2014	Deposition of Daniel Smith
2/11/2015	Trial testimony of Katrin Elbert